Invitation to take part in the SPIKE-1 Trial: A Phase II/III trial looking at the use of camostat to reduce progression of symptoms of coronavirus (COVID-19) in people who have tested positive but are able to stay at home.

PARTICIPANT INFORMATION DOCUMENT AND CONSENT FORM

The study is funded by LifeArc, a charity who help fund and develop academic research but is being run by Cancer Research UK. This research is only related to COVID-19 and it is important that it is clear that if you decide to join this trial, this is not because you have cancer. If you have any questions about this, please discuss with the research team.

This project is supported by Cancer Research UK. The Centre for Drug Development (CRUK-CDD) is experienced in running clinical trials and this expertise is being used to help the COVID-19 pandemic efforts. During this pandemic, CRUK-CDD researchers and collaborators across the UK have turned their expertise and resource towards COVID-19 research and this project is supported and sponsored by the Charity as part of that global effort.
Invitation to take part in the SPIKE-1 Trial: A Phase II/III trial looking at the use of camostat to reduce clinical progression of coronavirus (COVID-19) in people who have tested positive but are able to stay at home.

**Short Title: SPIKE-1 Trial**

- We are inviting you to take part in this research study, also known as a clinical trial because you have been identified as having coronavirus (COVID-19).
- You are free to decide whether or not to take part in this clinical trial.
- You can stop taking part in the trial at any time, without giving a reason, though the information we have already collected will be kept and used as part of this research and other research into COVID-19.
- Please feel free to ask us if there is anything that is not clear or if you would like more information on.

**Important things for you to know before reading further:**

We are currently looking at a drug called **camostat** as a possible treatment to help relieve symptoms of coronavirus (COVID-19).

Camostat is an oral tablet which has been used to treat pancreatitis (inflammation of the pancreas) in Japan since 1986. The clinical trial is randomised. A randomised trial means that some of the people who take part will receive camostat, and some will not. Neither you nor your doctor will be able to choose whether you receive camostat or not.

We cannot be sure if it will work in people with COVID-19 at this stage.

- Camostat is known to suppress a protein (part of the building blocks of every cell in your body) called serine protease that is required for the COVID-19 virus to infect human cells. We want to find out if camostat will block the entry of the COVID-19 virus into human cells and stop progression of the disease. This has been shown to be effective in COVID-19 in a small human trial in Japan and in animal studies for a similar type of virus.

- Camostat could have unwanted side effects. Side effects reported since the 1980’s are rare and for everyone who takes it, less than 1% (1 in 100) of patients will experience side-effects. These are typically mild (such as rash, pruritus [itching], nausea, and abdominal discomfort).

- Because you have tested positive for COVID-19 you will now be self-isolating. If you agree to take part in this clinical trial we will be relying on you to provide us with information about your symptoms. As part of this clinical trial you will monitor and document your symptoms at home, take your temperature and monitor your pulse rate and blood oxygen levels (we will discuss this later in this document). Someone from the research team will call you every day for 14 days, to check on your wellbeing, and someone may visit you at home a couple of times to take blood samples and other tests. Please note, the research team do not provide or replace usual clinical care.

- Not everyone who comes forward for this trial will be able to take part. The person you speak to will ask you some questions to make sure it would be safe (based on our knowledge of camostat) for you to take part.
• If you are randomised to not receive camostat then we will still contact you as mentioned above to check on your wellbeing and collect information about your symptoms.
• If you are randomised to receive camostat, then you must not share this drug with anyone else, it must only be taken by you.

If you would like to know more about this clinical trial and are interested in taking part, please read the rest of this document. It is important that you read it all and have the chance to ask questions.
How to contact us

If you have any questions about this trial, please talk to your doctor or nurse:

Name of doctor:
Hospital Department:
Hospital:
Address
Telephone: 01234 XXX XXX

Emergency contact details and those to be used if you decide to take part can be found in Section 21 of this document.
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Part 1

1 INVITATION

We would like to invite you to take part in this clinical trial. Before you decide whether to take part, you need to understand why the research is being done and what it would involve for you.

It is important that you take the time to read this information document carefully to decide whether or not you want to take part.

It is up to you to decide if you want to take part in this clinical trial. If you decide to take part, we will ask you to sign the consent form to show you have read this information sheet and agreed to take part.

2 WHAT IS THE PURPOSE OF THE CLINICAL TRIAL?

This clinical trial is looking at a drug called camostat. This drug has been used to treat patients with pancreatitis (inflammation of the pancreas) in Japan since 1986. We now wish to find out if it will be useful in treating patients with the coronavirus, also known as COVID-19.

The two main aims of this clinical trial are to find out:

- Whether camostat can reduce the need for people with COVID-19 requiring hospital admission or additional oxygen.
- Whether camostat has an effect on your COVID-19 symptoms, including body temperature, pulse rate and blood oxygen levels.

We aim to recruit about 400 people in this clinical trial which is being carried out across the UK.

We will review the trial results on an ongoing basis, and will formally review after the first 100 people have been enrolled, in what is called the pilot phase. After that review, we may decide to make changes to the trial before continuing to recruit further people.

3 WHY HAVE I BEEN INVITED TO TAKE PART IN THIS CLINICAL TRIAL?

You have been invited to take part in this clinical trial because you have been identified as having coronavirus (COVID-19) and are 50 years of age or over.

4 WHAT ARE THE ALTERNATIVE TREATMENTS?

A treatment called Remdesivir was approved in May 2020 for patients who had been hospitalised with severe COVID-19 infection. The use of Remdesivir is restricted to those patients who the clinicians feel have the greatest likelihood of benefitting.

At present, there is currently no approved treatment for patients with mild COVID-19 symptoms and who are able to stay at home and the best medical therapy in this scenario is supportive care as advised by the NHS.
If you are not eligible to take part in this clinical trial there might be other COVID-19 clinical trials that may be available to you. Please talk to the research team who will be able to discuss this with you further.

5 WHAT ARE THE POSSIBLE SIDE EFFECTS OF RECEIVING CAMOSTAT?

With any medicines there can be side-effects. We know that camostat has been used for over 30 years and the side-effects are mainly mild and have been seen in only a few patients. It is possible you may experience side effects and you will be monitored regularly for side effects on your daily phone/video calls with the research team. If you feel unwell or in any way different from usual while taking camostat please let a member of the research team know when they contact you, or by using the contact details provided in section 21.

The side-effects that have been seen in patients taking camostat for pancreatitis are rare and have been observed in less than 1% of patients (this means less than 1 patient in 100). Side effects are typically mild such as rash, pruritus (itching), nausea, abdominal discomfort, abnormalities in blood tests e.g. low number of blood cells called platelets (thrombocytopenia) or raised potassium in the blood (hyperkalaemia) and liver disorders (usually shows in blood tests).

A small number of patients in Japan have reported allergic type reactions. It is possible that participants in this trial may have a reaction to the drug, but the chances of this are very low. Allergic reactions typically feel like a tightness in the throat, swelling or tingling in the lips, difficulty in breathing or noisy breathing and if you experience this, you must stop taking camostat and call 999 immediately if the allergic reaction is severe.

If you take part in the clinical trial, you must report any medical problems you have to the research team when they call you. There is also a contact number given at the end of this information sheet for you to call if you become worried at any time.

If, for any of your oxygen saturation readings, the result is 94% or lower or if your pulse rate rises above 100 beats per minute (after sitting for 10 mins at rest), please repeat the readings. If either of the readings remains below 94% for your oxygen saturation levels or above 100 beats per minute, please directly contact your GP or call NHS 111 for advice. Please also contact your research team contact to let them know but your priority should be to contact your GP or NHS 111 first.

If you feel your symptoms are getting worse and you cannot breathe very easily then you must call your GP or NHS 111, or if the symptoms are really bad, then dial 999. Tell whoever you speak to that you are taking part in this clinical trial.

6 WHAT ARE THE OTHER POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

If you have life insurance, you should check if this will be affected by participating in this clinical trial. If you have private medical insurance, you should check with the insurer before agreeing to take part.
Harm to an unborn child from camostat

If you are a woman and there is a chance you could get pregnant, or if you are a man and there is a chance your partner could get pregnant please read the rest of this section.

If you are randomised to camostat, then you will need to take these precautions.

If you are not randomised to camostat, then these precautions do not apply.

If this does not apply to you, please go straight to the next section (Section 7).
For women:

Camostat might harm an unborn baby. You cannot take part in the clinical trial if you are pregnant or breastfeeding as there is a risk that large doses of camostat might suppress your baby's weight gain.

You should not take part in the clinical trial if you intend to become pregnant during the trial or during the four weeks afterwards.

If you do take part in the clinical trial and there is a chance you could get pregnant, then you must use appropriate medically approved contraception. If needed, a conversation about contraception will be held between you and the research team/clinician.

If you do become pregnant while taking camostat or within four weeks of your last dose of camostat you must tell your doctor immediately. Your doctor will talk to you about the possible risks to your unborn baby and they will offer you arrangements to monitor the health of both yourself and your unborn baby. Cancer Research UK will collect confidential information about your health and that of the baby from your trial doctor as they have a responsibility to report this to the regulatory authorities (the Medicines and Healthcare products Regulatory Agency [MHRA]) who have approved camostat for use in this clinical trial.

If you have any questions about this, please ask the research team.

For men:

Please share this information with your partner if it is appropriate.

It is not known if camostat will affect sperm or semen. Therefore, you must not father a child while taking part in this clinical trial and for four weeks after your last dose of camostat. If your partner could become pregnant you and your partner must use reliable forms of contraception; such as

- oral contraceptives and condom
- intra-uterine device (IUD) and condom
- diaphragms with spermicidal gel and condom

If your partner is pregnant or breastfeeding when you enter the clinical trial, you should use barrier method contraception (condom plus spermicidal gel) to prevent the unborn baby or the baby being exposed to camostat.

If your partner becomes pregnant whilst you are receiving camostat or within four weeks of your last dose of camostat, you should inform the clinical trial team immediately.

As the risk to your partner and baby is unknown, your clinical trial doctor will discuss with you the possible risks to your unborn baby and arrangements will be offered to monitor the health of both your partner and your unborn baby. Cancer Research UK will collect confidential information about your partner's health and that of the baby from your clinical trial doctor. Your partner will be asked to sign a consent form allowing your trial doctor to provide Cancer Research UK with this information so they...
can report this information to the regulatory authorities (the Medicines and Healthcare products Regulatory Agency [MHRA]) who have approved camostat for use in this clinical trial, as necessary.

If you have any questions about this, please ask the trial nurse or doctor.

7 WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

This purpose of this clinical trial is to find out information that may help people with coronavirus (COVID-19). There may be some benefit to you if you are randomised to take camostat, but this is unknown at this stage. If people develop more than mild symptoms, camostat may stop them becoming worse or may prevent the need for admission to hospital.

8 WHAT WILL HAPPEN TO ME IF I TAKE PART?

a) What tests do I need to have before I take part in the clinical trial?

Before you can take part in this clinical trial, we need to make sure it is safe for you to do so. To do this we start what we call ‘screening’, where the research team will ask you questions and perform some investigations. The results from the ‘screening’ process are checked against the trial eligibility criteria that you need to meet to be able to take part. It takes into account all the information we know about camostat and other similar drugs. This includes any medical conditions you may have or medicines that you are taking that would mean it was not safe for you to take camostat if you were randomised to do so. We need your consent to perform this ‘screening’ process, and only after we have done the ‘screening’ checks and assessments will we know if it is okay for you to take part in this clinical trial.

The screening process will include:

- An initial video/phone call with a member of the research team, so they can ask you a few questions about your symptoms and medical history.
- A home visit to perform a couple of tests which should take less than an hour. A member of the research team will visit you at home to perform the following:

<table>
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<tr>
<th>Test</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>Nose and throat swab</strong></td>
<td>This will be performed to check whether you have a positive COVID-19 infection. If you have already had a positive COVID-19 test confirmed then this does not need to be repeated.</td>
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<tr>
<td>(or other COVID-19 test)</td>
<td></td>
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<tr>
<td><strong>Blood sample</strong></td>
<td>A small blood sample (less than one tablespoon) will be taken from a vein in your arm for routine analysis. A further blood sample will be taken and will be stored for future research analysis (about a tablespoon). Both samples will be taken at the same time.</td>
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</table>

Only after you have completed screening will we be able to confirm whether or not you can take part in the clinical trial. The research team will call all screened participants to inform them of their results and whether or not they are eligible for the trial.
b) What is the randomisation procedure?

If you are eligible and you still want to take part, then you will be **randomised**.

A randomised trial means that not everyone who takes part will receive camostat. This allows us to compare the two groups against each other.

![Diagram showing randomisation process]

One in every two people will be selected using a computer programme to receive camostat. The people who are not selected will continue without camostat and their symptoms will be managed with best supportive care (this is care given by your GP and the NHS).

The people who are randomised to receive camostat will be asked to take 2 tablets, four times a day (each tablet equals 100 milligrams [mg] of camostat, so that is 200 mg four times a day). The box you receive your camostat in will clearly tell you what dose you are to take and how often. All participants, regardless of the randomisation will complete the assessments in the next part of this section.

We will review all the information we collect from the first 100 people to take part. After that review, we may decide to make changes to the trial before continuing to recruit further people.

You are free to leave the clinical trial at any time and you do not have to give a reason. If you decide not to take part, or you decide during the clinical trial that you no longer wish to take part, then that is fine and you will manage your symptoms as advised by your GP.
c) What will happen during the clinical trial?

Once you have been randomised, we will deliver the trial pack to you. The trial pack will include the following:

**Small plastic tubes:** to collect a sample of your saliva (spit) each day. You will need to keep hold of these until someone collects them (we may not need you to do this - your research team will confirm when you are randomised).

**A thermometer:** to measure your body temperature.

**A “pulse oximeter”:** this is a clip you place on the end of your finger to measure your blood oxygen levels and pulse rate.

**A copy of the questionnaire:** which will ask you various questions about your COVID-19 symptoms, our research team will go over this with you every day.

**A diary card:** you will use this to log your daily temperature, blood oxygen levels, pulse rate and the time you take your tablets and any side effects you might be experiencing.

If you are randomised to receive camostat, then the correct number of tablets you need to take over 14 days will be contained in the trial pack.

All participants will be asked to monitor their temperature using the thermometer, and their pulse rate and the amount of oxygen in their blood twice a day using the pulse oximeter. Someone will explain how the thermometer and pulse oximeter are used:

- You must use the thermometer to record your temperature **twice** a day around 12pm and 6pm. If you need to take paracetamol or any other medication which may bring down your temperature, then take your temperature first and the medication afterwards, or ensure your temperature reading is taken at least 3 hours after your last dose of medication. Record the readings in the diary card.

- Your pulse oximeter readings will need to be taken **twice** a day around 12pm and 6pm following a 10 minute rest. The pulse oximeter is to be placed on a finger for a minute or two and the reading tells us if your oxygen levels are normal or are low. Oxygen levels can be lower than normal and not need any treatment, but if they do drop too low, that is when supplementary oxygen is needed to help breathing. The pulse oximeter will also record your pulse rate. Record both the oxygen level and pulse rate readings in the diary card.

Because you will be at home during this time, someone will call you once a day, for 14 days to discuss your symptoms and they will ask you to give these readings over the phone/video call.

- They will ask you to review the questionnaire and report your COVID-19 symptoms plus any new symptoms you develop.
- You will need to use the diary card to help you to document the readings you take, and the time that you take your tablets (if you are randomised to camostat).
- You may be asked to take small saliva (spit) samples during the first 14 days. Not everyone will be asked to do this. Your research team will discuss this with you
when you are randomised. If we would like saliva samples to be taken, we will provide the tubes (in your trial pack) and you will be asked to keep these in your freezer at home until they are collected by a member of the research team.

- You will be asked to nominate a ‘Trial Partner’ that the research team can contact if you are not feeling well and cannot come to the phone. This can be someone else in your household or a next of kin.

The results will be entered onto a secure clinical trial database. It may not be the same person who contacts you each day and for this reason, your contact details are very important to us as we will need to make these available to the people who will make the calls. If you are not happy to share your contact details, please let us know.

Video/phone calls will be arranged for a time convenient for you, at around the same time each day. If you need to change this time for any reason, please let your research team know and they will call you at a time that works better.

After 7 days on the trial, and then again at 14 days, someone may visit you at your home to repeat the tests you had during screening.

- A nose and throat swab (or other COVID-19 test) will be performed to check whether you still have a positive COVID-19 infection.
- A small amount of blood will be taken and this will be sent to the hospital for routine analysis. (less than one tablespoon )
- A further blood sample will be taken to store for future research analysis (about a tablespoon).

The visits on Day 7 and 14 will not go ahead if e.g. you have been admitted to hospital or if the Sponsor decides that the research sampling is no longer required (if an adequate number of samples have been obtained from other participants). If this is the case, your research team will contact you.

If you are seen on Day 7 by a member of the clinical team and following discussion with your trial doctor, if your doctor feels you have recovered from COVID-19 then you may be able to stop taking the camostat tablets. Your doctor will discuss this with you at the time.

It is possible that additional blood may be taken throughout the duration of the trial for research purposes. The research team will discuss this with you at the time. The total amount of blood taken during the trial will not exceed 20 mL (less than 2 tablespoons). If further blood samples are needed in order to measure the levels of camostat in your blood, or understand how quickly the drug appears in your blood and how quickly your body the drug is excreted (removed), the research team will ensure they discuss this with you for your consent. They will explain how often blood samples are needed and how much blood will be taken. This will be documented in your medical notes.

The information that we have collected about you while you have been taking part in the trial will be kept in your diary card and reported to a member of the research team via video or phone calls for entry on the clinical trial database. The information (data) will be reviewed and analysed by Cancer Research UK (the Sponsor of the clinical trial). Please see Section 15.
d) What happens after I stop receiving camostat?

After you have finished the 14 days of camostat, we will continue to call you once a week for an additional 14 days. The research team will review the symptom questionnaire with you again, and will ask you to take your temperature and pulse oximeter readings. If you experience any side-effects from camostat as mentioned in Section 5 or have been admitted to hospital (all patients) we will need to follow-up with you or through your doctors for an additional 28 days. We may want to check in with you a year after you have taken part in the trial. We may need to contact you directly, or we may be able to get the information we need from your GP or local hospital.

At the end of the trial, your clinical research team will be in touch with you to collect the thermometer and oximeters from your home. Someone from the clinical research team may visit you to collect these or you may be provided with pre-paid packaging to send these back to the hospital.

9 CLINICAL TRIAL DESIGN

The clinical trial is in two parts. A ‘pilot’ phase and a ‘continuation’ phase. You will only take part in one phase.

**Pilot phase:** Approximately 100 participants will be randomised to one of two arms. They will receive camostat 200mg (two tablets) four times a day (total dose 800mg) or they will continue with no camostat and best supportive care at home. We will be looking at all the information that comes from all patients to make sure we can move to the ‘continuation’ phase. After we review data from the pilot phase, we may decide to make changes to the trial before continuing to recruit further people.

**Continuation phase:** All remaining participants will be randomised to one of two arms to receive camostat or no camostat with best supportive care.
### Participant Schedule & Checklist:

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<th>Assessment</th>
<th>Screening</th>
<th>Day 1</th>
<th>Days 1-7</th>
<th>Day 7</th>
<th>Days 8-14</th>
<th>Day 14</th>
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* - Research team will confirm if home visit takes place
** - Your research team will let you know if you have to do this

- Participant responsible
- Research team responsible

### 10 WILL I BE PAID TO TAKE PART?

You will not be paid for taking part in this clinical trial. However, if you need to travel to see a doctor or nurse, we will pay reasonable travel expenses for you and a trial partner.
11 WHAT DO I HAVE TO DO?

You need a level of commitment when you take part in a clinical trial. If randomised to the treatment group, you will need to take camostat 4 times daily, for 14 days.

For all patients, regardless of what group you are randomised to, you must keep an accurate record of your time on the trial in a diary card, and report these to the research team who will call you daily. You will also need to allow three home visits, the first one to carry out screening assessments and the other two so we can take some additional tests. Section 8 in this information document explains what you will need to do if you take part in the clinical trial.

There are no specific restrictions on what you can eat, drink, or do. If you are randomised to take camostat, you will need to take the tablets after a meal or small snack. You must let your clinical trial team know if you have any hypersensitivities or allergies.

There are instructions on how to take camostat on your diary card, as well as information on what to do if you miss a dose or if you vomit.

We do ask that if you are taking any medicines to lower your temperature, such as paracetamol, that you take your temperature at least three hours after you have taken the medication or just before you take the medication.

If you decide to take part, we will give you a small card that shows you are taking part in this clinical trial. While you are taking part in the clinical trial, you should always carry this card with you. If you need to speak to your GP, NHS 111 or go to Accident and Emergency, then you should take this card with you and let the person you speak to know you are participating in this trial.

12 WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE ABOUT CAMOSTAT?

During this clinical trial we may learn important new information about side effects (safety information) and the general effects of camostat when given to people with COVID-19. If this happens we will tell you about it and discuss with you whether you want to continue in the clinical trial. If you decide to leave the clinical trial, your trial doctor will arrange for your care to continue. If you decide to continue in the clinical trial you may be asked to sign an updated consent form.

On receiving new information, we might consider it to be in your best interests to withdraw you from the clinical trial. If this is the case, we will explain why and arrange for your care to continue.

13 WHAT WILL HAPPEN IF I DON’T WANT TO CARRY ON WITH THE CLINICAL TRIAL?

If you leave the clinical trial, you must inform the research team via the contact details provided. We will keep records about what happened while you were taking part, up until the point you decided to leave the clinical trial. If you are experiencing any side-
effects because of camostat, we will follow these up until they resolve. We may need to contact you about this or be able to get this information from your health records. **This is important to understand.** You do not have to continue taking part, but we have to follow-up any problems with camostat as this could help future use of the drug. So with your consent we may need to collect some follow-up information.

Any blood samples taken as part of this trial will be kept and analysed. As with all your information the results will be kept confidential and your name will not be used. You may not receive the results of the blood tests as these are for research purposes but if any results mean you might need to stop camostat, or if the research staff were worried about them, these would be discussed with you.

### 14 WHAT IF THERE IS A PROBLEM?

**Complaints:**

If you have a concern about any aspect of this clinical trial, you should ask to speak to a member of the research team or the clinical trial doctor, who will do their best to answer your questions. The contact number is given at the end of Part 2 in Section 211. If you are still unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Local details for formal complaints are as follows: `<local details to be added>`.

NHS Trusts/Boards are responsible for clinical negligence and other negligent harm to individuals that are under their duty of care. This means the NHS Trust/Board is responsible if the care you received fell below medically acceptable standards, and this directly caused you to be injured.

**Harm:**

Compensation for any serious injury caused by taking part in this clinical trial will be in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). Copies of these guidelines are available on request.

**ABPI guidelines in summary:**

- Broadly speaking, the ABPI guidelines recommend that “the Sponsor”, without legal commitment, should compensate you providing you can show, on balance, the injury arose from your taking part in the clinical trial without you having to prove that the sponsor is at fault. This applies in cases where it is likely that such injury results from giving any camostat or any other procedure carried out in accordance with the protocol for the trial.

- The Sponsor of this clinical trial is Cancer Research UK and it will arrange compensation in accordance with the ABPI guidelines. Cancer Research UK will not arrange compensation for you where such injury results from any procedure carried out which is not in accordance with the protocol for the clinical trial or the injury is caused by the negligence of a third party (including a doctor’s failure to deal adequately with a side effect).
• Your right at law to claim compensation for injury where you can prove negligence is not prevented.

• In deciding the level of compensation to be awarded, consideration will be given to the seriousness of the disease being treated, how likely that side effects will occur and any warnings that were given.

• This undertaking to provide compensation extends only to injury arising during the course of the clinical trial, but not to injury caused by treatment extended beyond the end of the clinical trial commenced by the Investigator.

15 WILL MY TAKING PART IN THIS CLINICAL TRIAL BE KEPT CONFIDENTIAL?

If you agree to take part in this clinical trial, the trial doctors and research teams will collect information about you while you are taking part. We may also collect information on what has happened to any side-effects you may still have because of camostat when you come off study and what other treatments you may have, this may include X-Rays, CT Scans and other routine tests performed due to your COVID-19 infection. Someone will be calling you daily whilst you are on study, therefore your contact details will be very important to us. You will be asked to provide a phone number and email address for a Trial Partner, who may be contacted by the research team if you are unavailable. These phone numbers will be shared within your research team, but will not be shared externally. The phone calls may be recorded for monitoring purposes, and will only be accessible by the trial medical experts and not the trial sponsor. You will be asked at the start of any video/phone call, if you consent to recording. You can say no to the recording and still take part in the trial. Any recordings will be held securely by your clinical research team and destroyed at the end of the pilot phase of the study.

This information, as well as related health records will be documented in your medical records. As with all NHS records, it will stay strictly confidential. However, these records will need to be looked at by researchers authorised by Cancer Research UK and Ono Pharmaceuticals (the company who make camostat). People from Regulatory Authorities may also need to look at this information. This is so they can all check that the clinical trial is being carried out correctly.

Information about you will be entered onto Cancer Research UK’s clinical trial database. This database is managed and maintained by Cancer Research UK and only accessible by your trial doctor, certain members of their team and by members of staff employed by Cancer Research UK. This information will not include your name or address but will record your gender (male or female), initials and date of birth. You will also be allocated a clinical trial number.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from (leave) the clinical trial, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information (e.g. name, contact details, date of birth etc) possible.
If we have to send any information about you, we will remove your name, address, hospital number and other personal information so you cannot be recognised. You will only be identified by your initials, date of birth and a trial number. We will include your date of birth (where necessary) as this is required if we need to report any side-effects you may experience to the Research Ethics Committee (who approved this clinical trial) and the Medicines and Healthcare products Regulatory Agency (MHRA) who oversee all clinical trials in the UK. We also need your date of birth because some blood tests have different result ranges depending on your age. By signing the consent form at the end of this document you agree to information about you being used for the current clinical trial and for any further research carried linked to this clinical trial, even if you leave the trial.

The information collected and held by Cancer Research UK will be looked at closely. Cancer Research UK will take all necessary steps to protect the confidentiality of your data.

At any time in the future, authorised people within Cancer Research UK, as well as regulatory authorities, pharmaceutical companies or researchers in the UK and other countries may want to look at the information. Cancer Research UK will share the information that comes out of this clinical trial. This information or data, may not directly help to develop camostat further, but may help researchers in other ways.

Anonymised information collected on the clinical trial database or from the analysis of research samples taken during this clinical trial may be transferred within or outside of the European Economic Area. Cancer Research UK is responsible for ensuring compliance with the European Union’s General Data Protection Regulation (GDPR) of 2018 and protection of your privacy. The information collected will be kept by Cancer Research UK for at least 25 years after the clinical trial has closed.

16 INVOLVEMENT OF YOUR GENERAL PRACTITIONER (GP) AND OTHER DOCTORS YOU MAY NEED TO SEE

We will let your GP know you are taking part in this clinical trial. We will give them information about camostat and what side-effects you may have. Please make sure you always carry the card you will be given to say you are taking part in this clinical trial. This card has contact details for your clinical trial doctor should they be needed.

17 WHAT WILL HAPPEN TO ANY SAMPLES I GIVE?

Routine blood samples will be analysed at the hospital laboratories. The results will be made available to your clinical trial doctor and the samples will then destroyed according to hospital policy.

For the trial specific research samples (nasal swabs, bloods and saliva), we may need to send these to a central laboratory. The samples will be analysed and may be kept to help future research into COVID-19. Some of the tests which we would like to do on the research samples are still being developed and we are still finding out information on which are the best tests to do. This means that some of the research samples you give will be stored until a decision is taken to analyse them. If it is decided not to
analyse these samples during the trial they may be used in other ethically approved research.

At the end of the trial, once the results are finalised, any remaining samples (including those that were not analysed) will be considered a ‘gift’ unless you tell us otherwise and there is a question for you to answer about this on the consent form at the end of this document. If you are happy to ‘gift’ these left over samples, they will be ‘unlinked’ (your trial number and initials will be removed from the label). The samples will be stored and used for future research. If these samples cannot be used, then they will be destroyed.

**Genetic tests**

Some of the research samples we take may be used for genetic tests. This genetic research may help us understand why camostat helps some people more than others.

The results of the genetic tests are used for research purposes only and the results will not affect your health or medical care. All results will be kept confidential and your name will not be used.

### 18 WHAT WILL HAPPEN TO THE RESULTS OF THIS CLINICAL TRIAL?

Soon after the trial has started, the details of the clinical trial will be on the Cancer Research UK website at the link below. This website will be updated with information during the trial. Once the trial has finished, the results of the clinical trial will be written up and will be published here. If you do not have access to the internet, you can ask the research team to give you a paper copy of the results.

The website can be found here: [www.cruk.org/spike1](http://www.cruk.org/spike1)

The results are usually also published in a medical journal. You will not be identified in any report or publication.

You will not have the right to share in any profits that may arise from research in this clinical trial.

### 19 WHO IS ORGANISING AND FUNDING THIS CLINICAL TRIAL?

This clinical trial is being organised by Cancer Research UK’s Centre for Drug Development alongside researchers across the country. The study is funded by LifeArc, a charity who help fund and develop academic research. Ono Pharmaceutical Co Ltd will be supplying camostat for use in this trial. The hospital may be reimbursed to cover the costs of the specific clinical trial tests or visits to your home.

### 20 WHO HAS REVIEWED THE CLINICAL TRIAL?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. The Research Ethics Committee has reviewed and approved this clinical trial. This means they agreed this clinical trial meets ethical standards and the clinical trial could go ahead.
The Medicines and Healthcare products Regulatory Agency (MHRA) have approved the use of camostat for this clinical trial.

21 FURTHER INFORMATION AND CONTACT DETAILS

If you need any further information or have any concerns while taking part in this clinical trial, please contact one of the following people:

<site to add contact numbers of investigator(s), for research nurse(s) - contact number only as research nurses change more than investigators>, emergency contact number, or any other relevant person at the trial site to contact for information. Make sure these are consistent with details on cover page>

If you take part in this clinical trial you will be given a copy of this information sheet and a copy of the signed consent form to keep.

Thank you for taking time to read this Information Document
SPIKE-1 TRIAL

CONSENT FORM
– consent for taking part in a clinical trial

SPIKE-1 Trial: A Phase II/III trial looking at the use of camostat to reduce clinical progression of coronavirus (COVID-19) in people who have tested positive but are able to stay at home.

In order to take part in this clinical trial, you must write your initials in each box. If you feel you are unable to initial all of the boxes, please discuss this with the research team.

Please initial every box

• I confirm that I have read and I understand the information sheet dated 08 June 2020 (version 2.0) I have had the opportunity to consider the information, ask questions and I have had these answered satisfactorily.

• I understand that I do not have to take part in this clinical trial if I do not want to and that I am free to leave the trial at any time. This will not affect the quality of my medical care or my legal rights.

• I understand this trial is randomised so I do not get to choose if I receive camostat or not. I understand I can still change my mind about taking part at any time.

• I understand that authorised individuals from Cancer Research UK or from Regulatory Authorities may look at my medical records. This is to check the clinical trial is being carried out correctly. I give permission for them to look at my medical records for this clinical trial and for any further research carried out which is linked to this trial, so long as strict confidentiality is maintained.

• I understand that information about my past medical history and medication I am taking will be collected as part of this clinical trial. I also understand that full details of my participation in this clinical trial, including results of investigations, COVID-19 symptoms, side-effects (related or unrelated to camostat) and medications I may be given, will be collected and entered into a secure database for this clinical trial. My initials and date of birth will be recorded on this database as well as my gender. My phone number will be used by the research team, but strict confidentiality will be maintained and I will not be identifiable to anyone outside of the research team looking after me.
CONSENT FORM
– consent for taking part in a clinical trial

SPIKE-1 Trial: A Phase II/III trial looking at the use of camostat to reduce clinical progression of coronavirus (COVID-19) in people who have tested positive but are able to stay at home.

In order to take part in this clinical trial, you must write your initials in each box. If you feel you are unable to initial all of the boxes, please discuss this with the research team.

Please initial every box

- I agree that information about me can be collected, analysed, reported, and shared with others within and outside the European Union (EU) as part of healthcare and/or medical research. I understand that my name will not be used and I will not be identified.

- I agree to give blood samples and research samples as described in the information sheet, for use in this clinical trial and for future research.

- OPTIONAL: I agree that at the end of the trial if there are any remaining blood samples that I have given during the study, then these will be gifted, and stored for future research.

- I agree to give blood and research samples for genetic tests, as described in the information sheet, for use in future research. I understand that the results of these investigations are unlikely to have any implications for me personally.

- I understand that if I choose to leave this clinical trial, the information collected about me can still be used and that any follow-up information e.g. such as updates on my COVID-19 symptoms and any side-effects caused by camostat may still be collected and shared with Cancer Research UK.
CONSENT FORM
– consent for taking part in a clinical trial

SPIKE-1 Trial: A Phase II/III trial looking at the use of camostat to reduce clinical progression of coronavirus (COVID-19) in people who have tested positive but are able to stay at home.

In order to take part in this clinical trial, you must write your initials in each box. If you feel you are unable to initial all of the boxes, please discuss this with the research team.

Please initial every box

• I understand that my GP, and other doctors treating me, will be told I am taking part in this clinical trial and that they may be contacted for further information about my health status up to one year after I have joined the study.

• I understand that recordings will be made of the video/phone calls and that I can decline these recordings at any point without it affecting my participation in the trial.

For female patients only: I understand that should I become pregnant whilst receiving camostat or within 4 weeks of me receiving my last dose of camostat that Cancer Research UK will collect information about my pregnancy, my health and that of my child

For male patients only: I understand that should my partner become pregnant whilst I am receiving camostat or within 4 weeks of me receiving my last dose of camostat that Cancer Research UK will request collection of information about my partner’s pregnancy, my partner’s health and that of my child.

OPTIONAL: I do not have access to the internet. Please provide a paper copy of the results when the time comes.

• I agree to take part in this clinical trial.
Signatures:

Name of participant ___________________________ Signature ___________________________ Date ___________________________

(This section must be completed by the participant)

Name of Investigator/Doctor taking consent ___________________________ Signature ___________________________ Date ___________________________

Important information for those Investigators/sub-investigators taking consent:

Please ensure that if you are taking informed consent you have completed the trial specific delegation log.

Once the Consent Form has been completed:

Researchers to file original where possible (copy acceptable) and participant to keep a copy. File/upload a copy in the participant’s medical records.