ADD LOGOS

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MulTi-Arm Therapeutic study in pre-ICu patients admitted with Covid-19 – Experimental drugs And mechanisms (TACTIC-E)

NEXT OF KIN / PERSONAL LEGAL REPESENTATIVE

Introduction

We would like to invite your relative/friend to take part in this trial.

However due to their condition your relative / friend is unable to decide for himself/herself whether to participate in this research. We therefore would like to ask you to provide consent on behalf of your relative/friend to participate in this study. To help decide if he/she should join the study, we would like to ask you to consider what you know of their wishes and feelings, to consider their interests and to try to set aside your own personal views when making this decision. Somebody who undertakes this role is called a **personal legal representative**. In case a personal legal representative is not available, an independent health care provider will be nominated to act as a **professional legal representative**

Please let us know of any advance decisions they may have made about participating in research. These should take precedence. If you decide your relative / friend would have no objection to taking part we will ask you to read this information sheet and sign the consent form on the last page of this information leaflet to give consent on behalf of your relative/friend to participate in the TACTIC E study. We'll then give you a copy to keep. We will keep you fully informed during the study so you can let us know if you have any concerns or you think your relative/friend should be withdrawn.

If you decide that your relative/friend would not wish to take part it will not affect the standard of care they receive in any way.

If you are unsure about taking on this role you may seek independent advice.

We will understand if you do not want to take on this responsibility.

PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM

Your relative / friend is being invited to take part in a research trial. Before deciding whether to take part, you need to understand why this research is being done and what it involves. Please take time to read the following information carefully and talk to others about the trial if you wish. Please ask us if anything is not clear or if you would like more information. Please take time to decide whether or not you wish your relative / friend to take part.

Section 1 tells you the purpose of this trial and what will happen to your relative/friend if they take part.
Section 2 gives you more detailed information about the conduct of the trial.

Section 1: Purpose of the trial and what will happen

1. What is the purpose of the trial?

COVID-19 was declared a pandemic on 11th March 2020 by the World Health Organisation (WHO). It is a disease affecting the lungs, and is caused by a new coronavirus known as SARS-CoV2. Most people with the virus have mild symptoms. However, some people, for example older adults and those with underlying health conditions including heart disease and diabetes, may develop more severe symptoms, leading to hospitalisation, increased support for breathing (e.g. use of a ventilator in an intensive care unit) or even death. There are currently no vaccines against the virus, or proven treatments to treat it.

Some of the severe symptoms of the virus are thought to be a result of an overactive immune response, leading to organ damage in the body. The purpose of this trial is to determine the best way to treat patients with COVID-19 infection by comparing different treatments which act on the immune system, with the aim of reducing severe symptoms and therefore the number of Intensive Care Unit (ICU) admissions in hospital.

2 What are the drugs being tested?

The treatments are:

1) EDP 1815 – is a microbe found in human intestines which is thought to have a calming effect on an overactive immune system
2) Ambrisentan and Dapagliflozin, two different drugs, each taken as a single capsule once daily. Ambrisentan is a licensed drug which targets the walls of blood vessels in the lungs and blunts inflammatory activity in the lungs. It is commonly used to treat a condition known as pulmonary arterial hypertension. Dapagliflozin is another licensed drug which helps the kidneys excrete glucose and it is commonly used in type 2 diabetes mellitus.

All trial participants will receive standard of care. Both types of trial treatments are being compared to being on standard care only. Some patients will be randomised to standard care arm only (which may include standard antivirals), that is without any new drug.

TACTIC-E will use a platform design. A "platform trial" is a clinical trial with a master protocol, which allows for multiple treatments to enter or exit the trial over the course of the study. This means that the trial team can, with interim analyses, stop recruiting to treatment groups (arms) early where a clear early decision can be made. It also allows for the addition of further arms and treatments. If the treatment your relative/friend have been assigned to is stopped, they will immediately stop treatment.

3 Why has your relative / friend been invited to take part?

Your relative / friend has been invited to participate in this trial because they have or are suspected to be COVID-19 positive, are considered to be at higher risk of developing serious symptoms, and who we believe Ambrisentan and Dapagliflozin or EDP1815 may be suitable treatments.

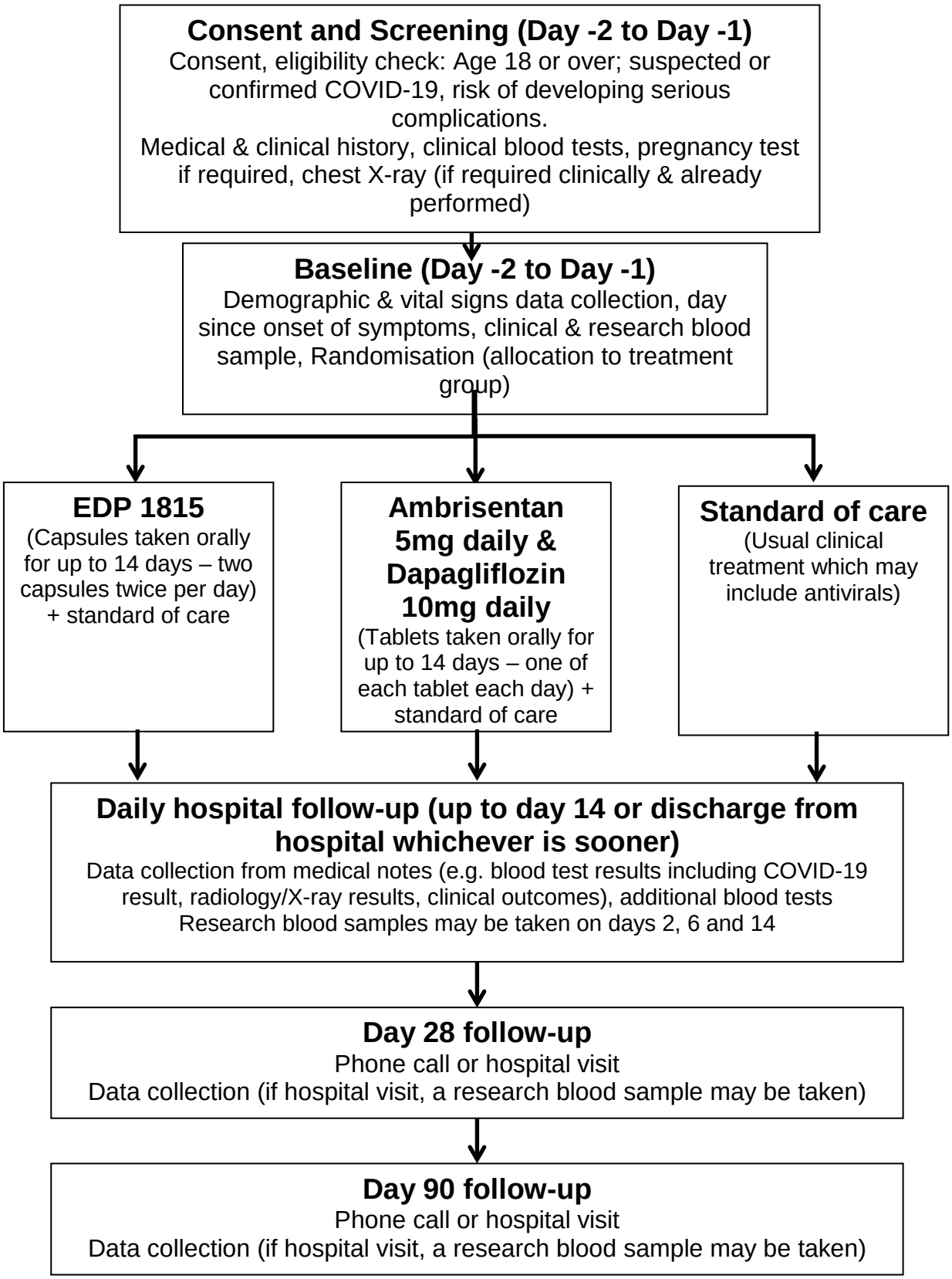
We plan to include up to 496 participants (in each arm) with COVID-19 disease from a number of hospitals across the UK.

4 Does my relative / friend have to take part?

No, participating in this trial is completely voluntary. If you decide on your relative / friend's behalf for them to participate, you will be asked to sign an Informed Consent Form, however you are still free to change your mind and you may withdraw your relative/friend from this study at any time without giving a reason. If you choose that they will not participate or wish them to leave the trial, their future medical treatment will not be affected in any way. A member of the trial team will discuss the trial with your relative / friend, to obtain their consent, if your friend / relative is able to do so before discharge.

5. What will happen to my relative / friend if they take part?

The following flowchart summarises the trial:



There are 3 groups in this study; one group gets the normal treatment (standard of care) and two groups which will each receive a different treatment. As we don't know whether EDP 1815 or combination Ambrisentan and Dapagliflozin on top of standard of care can be used to treat COVID-19 related disease, we need to compare the treatments separately to regular standard of care. The trial treatments mentioned above will be in addition to your relative / friend's usual clinical care. Please note, all assessments up to day 14 are conducted at the hospital either up to day 14 or up unitl discharge from hospital whichever is sooner.

Consent and screening (approximately 45 minutes): If you agree for your relative / friend to participate in the trial, you will sign the Informed Consent Form at the end of this document and be given a copy of this to take away and refer to later. The screening assessments include checking your relative / friend's clinical and medication history, checking that they are suitable for the trial, and reviewing blood tests that they have had since admission to hospital. If the blood tests have not yet been done, these will be taken and checked. The screening process may happen up to 48 hours before trial treatment begins. However, since COVID-19 requires urgent treatment, where urgency is needed, screening and baseline procedures can happen on the same day.

Baseline (duration, approximately 45 minutes): Further routine clinical information from your relative / friend's medical notes will be collected. A blood sample (blood group, serum and DNA/genetics biomarkers, sample for future analysis may be taken; the maximum amount of blood taken will be approximately 30ml [2 tablespoons]). Following this, they will be randomised to a treatment group.

Randomisation: Brief details identifying your relative / friend and the answers to a few questions about your relative/ friend's health and medical conditions will be entered into a computer. The computer will then allocate your relative / friend at random (like rolling a dice) to one of the possible treatment options. In all cases the treatment groups will include the usual standard of care for their hospital. This trial will randomise patients in a 1:1:1 format. This means that for every one patient randomised into the standard of care arm, one patient will be randomised into each of the other treatment groups.

Treatments and In-hospital follow-ups (days 1-14, or up to discharge from hospital, whichever is sooner): Following random allocation to a treatment group, treatment will commence. The options are:

1) EDP 1815 (an unlicensed drug (human-derived bacterium) which is being developed for the treatment of inflammatory diseases; it acts by modulating the immune system)
2) Ambrisentan and Dapagliflozin (Ambrisentan is a licensed drug which targets the walls of blood vessels in the lungs and blunts inflammatory activity in the lungs. It is commonly used to treat a condition known as pulmonary arterial hypertension. Dapagliflozin is a licensed drug which helps the kidneys excrete glucose and it is commonly used in type 2 diabetes mellitus)
3) Standard of care (usual clinical care for COVID-19 infection which may include antivirals)

We will collect information from your relative / relative's medical notes about how they are doing, their vital signs, what blood tests and x-rays/scans they have had during their hospital stay, and the results of these. Depending on the group that they are in we may run additional tests to monitor the acid levels in their blood. On days 2, 6 and 14, research blood samples may also be taken, to look at immune cells and markers in the blood. We will take a maximum of 30ml of blood (2 tablespoons).

Day 28 and day 90 Follow-up (Telephone call or hospital visit): We will be asking you or your relative / friend (if they regained capacity) a few questions about their health and collecting data from their medical notes. If your relative / friend visits the hospital we may also take a further research blood sample and collect data from other clinical tests such as chest X-rays or lung function tests if they are performed as part of your relative / friend's standard of care.

6. What will they have to do?

This trial will run during your relative / friends stay in hospital. Depending on the treatment group that they are allocated to, the drugs have different dosing regimens. These are described briefly in the trial flowchart, and in more detail below:

EDP 1815:

This drug is taken as capsules orally for 7 days; the trial doctor may extend your relative / friend's treatment up to 14 days – if it is felt that they are responding to treatment. They will be taking two capsules twice a day. Each dose should be taken without food and food should not be consumed for one hour after administration. There should be at least two hours between the twice-daily doses. If your relative / friend improve and are discharged before this time, the treatment will be stopped.

Ambrisentan:

This drug is taken as a tablet once a day for up to 7 days whilst they are an inpatient; the trial doctor may extend your relative / friend's treatment up to 14 days if they remain as an inpatient – if it is felt that they are responding to treatment. The tablet may be taken with or without food and is to be swallowed whole. If your relative / friend improve and are discharged before this time, the treatment will be stopped.

Dapagliflozin:

This drug is taken as a tablet once a day for up to 7 days whilst they are an inpatient; the trial doctor may extend your relative / friend's treatment up to 14 days if they remain as an inpatient – if it is felt that they are responding to treatment. The tablet may be taken with or without food and are to be swallowed whole. If they happen to be randomised to this arm, the acid levels in their blood will be monitored. If they improve and are discharged before this time, the treatment will be stopped.

You should tell the trial team if your relative / friend feel unwell or different in any way. If you have any major concerns about your relative / friend or they are feeling very unwell please contact their trial doctor immediately. If they have been discharged from hospital please contact the trial doctor using the contact numbers at the end of this information sheet.

Following discharge from hospital, we may ask you to accompany your relative/friend to the hospital or be available to talk on the phone for their day 28 and day 90 follow-up visits. If these visits happen at the hospital we may ask your friend/relative for further clinical and research blood samples.

You should discuss your relative / friend's participation in this study with any insurance provider they have (e.g. protection insurance, life insurance, income protection, critical illness cover and private medical insurance) and seek advice if necessary, as failure to notify them may affect or invalidate their cover.

7. What are the side effects of the drugs?

EDP 1815:
No specific side effects have been described with EDP 1815.
Ambrisentan:
Very common (more than 10 in 100 of patients): headache, peripheral oedema, fluid retention.
Common (less than 10 in 100 of patients): anaemia, dizziness, cardiac failure, palpitations, low blood pressure, flushing, nosebleeds, difficulty breathing, upper respiratory congestion, nausea, vomiting, diarrhoea, abdominal pain, constipation, increased liver enzymes (transaminases), chest discomfort or pain, lack of energy, fatigue.
Uncommon (less than 1 in 100 of patients): hypersensitivity reactions, e.g. angioedema (swelling under the skin) rash, itchiness, fainting, autoimmune hepatitis, liver injury

Dapagliflozin:
Very common (more than 10 in 100 of patients): hypoglycaemia (low blood sugar when used with insulin or sulphonylurea drugs).
Common (less than 10 in 100 of patients): genital infections, urinary tract infections, dizziness, rash, back pain, painful or difficult urination, increased urine output, blood test results which show an increase in haematocrit (increase in the volume of red blood cells in your whole blood), decrease in creatinine renal clearance, which indicates kidney function, or dyslipidaemia (changes in the fat concentrations).
Uncommon (less than 1 in 100 of patients): dehydration, hypotension and thirst, dry mouth and constipation, nocturia, genital pruritus, and blood test results which show an increase in blood creatinine and urea levels, which indicate kidney function and decreased weight.
Rare (less than 0.1% of patients): diabetic ketoacidosis
Very rare (less than 0.01% of patients): fournier's gangrene, angioedema (swelling under the skin)

8. What are the possible disadvantages and risks of taking part?
Blood tests: Occasionally, some bruising or inflammation at the needle site may occur and very rarely infection at the puncture site.

Drug treatment:
Both Ambrisentan and Dapagliflozin are given to patients in the UK and are well tolerated. However, individual patients can react differently to a particular drug which means that there is a possibility of experiencing side effects. The trial doctor will monitor any side effects regularly and take appropriate actions where necessary. In this trial ambrisentan is

administered in conjunction with dapagliflozin (two different types of drug) both to offset any negative effects of fluid re-distribution in those with COVID-19 and because patients may derive further benefit from dapagliflozin therapy.

There are no clinical data available of the effects in pregnancy for either Ambrisentan or Dapagliflozin. However, animal studies of Ambrisentan have shown toxicity to the foetus and animal studies of Dapagliflozin suggest toxicity to the foetus. Ambrisentan is contraindicated in pregnancy and Dapagliflozin is not recommended to be taken by pregnant women.

EDP1815 is a single strain of a bacterium which is often found in your gut. EDP 1815 does not cause infections, is not genetically modified, does not persist in the gut, and does not alter the normal bacteria in your gut. EDP1815 acts locally in the gut without being actually absorbed- but has effects throughout the inside of the body modulating your immune system without getting into the blood. These medicines are therefore very well tolerated. One of the key reasons for selecting EDP1815 as an arm in this study is due to its safety profile, which would be particularly beneficial in the COVID-19 population as there is no evidence that it increases the risk of infection due to its novel and unique mechanism of action. EDP1815 is currently in phase 2 clinical development and has European and US approval to initiate a multinational psoriasis study, scheduled for the second half of 2020. There are no clinical data available of the effects in pregnancy for EDP 1815.

Your relative/friend should not participate in this trial if you are aware that they are planning to become pregnant or father a child during the trial. Women who are able to have a baby must use one of the following reliable forms of contraception for the entire duration of the trial (90 days) after upon completion of the last treatment

This includes:

- Intrauterine Device (IUD)
- Hormonal based contraception (pill, contraceptive injection or implant etc.)
- Barrier contraception (condom and occlusive cap e.g. diaphragm or cervical cap with spermicide)
- True abstinence (where this is in accordance with the participants' preferred and usual lifestyle)

Men are required to use adequate contraception for the entire duration of the trial (90 days) upon completion of the last treatment. This includes:

- Barrier contraception (condom and spermicide) even if female partner(s) are using another method of contraception or are already pregnant (also to protect male partners from exposure to the trial IMPs etc.)
- True abstinence (where this is in accordance with the participants' preferred and usual lifestyle)

If your relative/friend becomes pregnant during the trial (within 90 days) after completion of the last treatment, they should inform their trial doctor immediately.

Your relative/friend should discuss your participation in this trial with any insurance provider they have (e.g. protection insurance, life insurance, income protection, critical illness cover and private medical insurance) and seek advice if necessary, as failure to notify them may affect or invalidate their cover.

9. What are the possible benefits of taking part?

There is no guarantee that your relative / friend will benefit from taking part in this trial. However, information collected as part of their participation in this trial may benefit patients with COVID-19 in the future.

10. What are the alternatives for treatment?

There are no known preventative drugs for COVID-19 currently.

11. What will happen if your relative / friend become very ill and can no longer take the tablets?

If your relative / friend becomes very unwell or confused during the trial but can continue to swallow the treatment tablets, will we continue with the treatment and blood tests. When they are better we will check with them that they did want to and wished to stay in the trial.

If your relative / friend become so unwell that they cannot swallow the treatment tablets their participation in the trial will stop. We will keep the information that we have collect about your relative / friend up until this point, but not after this point.

12. What happens when the trial stops?

Once the trial has ended your relative / friend will be referred back to regular treatments. Pending the results of the trial, treatment guidelines may change.

13. Expenses & Payment?

Your friend / relative will be reimbursed travel expenses for any research visits which require them to attend hospital after they have been discharged.

14. Optional Endothelial cell collection

In some centres, we are also conducting a smaller study for patients participating in the main study. We will provide you with an additional information sheet and consent form describing an optional procedure called Endothelial Cell Collection. Your relative/friend can still take part in the TACTIC-E trial if you choose for them not to take part in the endothelial cell collection.

Section 2: Trial Conduct

15. What if new information becomes available?

Sometimes during the course of a trial, new information becomes available which might affect your decision for relative / friend to continue participating in this trial. Their trial doctor will contact you to discuss the new information and whether you wish for them to continue participating in the trial. If you still wish your relative / friend to continue on the trial, you will be asked to sign a new Informed Consent Form. The trial sponsor, the regulatory authority or the trial doctor may decide to stop the trial at any time. If that happens we will tell you why the trial has been stopped and arrange for appropriate care for your relative / friend.

16. What if I decide I no longer wish my relative / friend to participate in the trial or they decide they no longer wish to participate in the trial?

Your relative / friend are free to come off this trial at any time without giving a reason and without affecting their future care. If you decide that they will not participate any further, they will no longer receive the trial treatment. No further tests will be performed on your relative / friend and no further research samples will be collected. Any data already collected or results from tests already performed on your relative / friend or samples already collected will continue to be used in the trial analysis.

The trial doctor may also choose to withdraw your relative / friend from the trial if they feel it is in their best interests or if they have been unable to comply with the requirements of the trial. Reasons for trial withdrawal could include:

- They have experienced a serious side effect
- They are unable to complete the visits, medication or trial documentation as required
- The trial doctor feels they no longer appear to benefit from the treatment

If they have experienced any serious side effects during the course of the trial which requires them to withdraw from the trial, their trial doctor will follow-up with them regarding their progress until the side effect has stabilised or resolved.

17. What if there is a problem?

Any complaint about the way your relative / friend has been dealt with during the trial or any possible harm that they might suffer will be addressed. If you have any concerns about any aspect of this trial you should speak to the trial doctor who will do their best to answer your questions. In the event that something does go wrong and your relative / friend is harmed by taking part in the research and this is due to someone's negligence then they may have grounds for a legal action for compensation against Cambridge University Hospitals NHS Foundation Trust (your hospital – for multicentre trials). If their claim is successful, their legal costs will be met. The normal National Health Service complaints mechanisms will still be available to them (if appropriate).

The NHS does not provide no-fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm. They are able to consider an ex-gratia payment in the case of a claim. If you wish to complain or have any concerns about any aspect of the way your relative / friend has been approached or treated during this trial, you can do this through the NHS complaints procedure. In the first instance it may be helpful to contact the Patient Advice and Liaison Service (PALS)) at the hospital. Their details are (add site PALS contact details here).

18. Will their taking part in this trial be kept confidential?

For participants recruited at CUH (where the Sponsor is also the site):

Cambridge University Hospitals NHS Foundation Trust (CUH) is the Sponsor for this clinical trial based in the UK. They will be using information from your relative / friend and their medical records in order to undertake this trial and will act as the data controller for this trial. This means that they are responsible for looking after your relative / friend's information and using it properly. The Sponsor organisation will keep identifiable information about your relative / friend for 5 years after the trial has finished ensuring their safety and allowing the trial to be reviewed by the authorities after it is finished.

Your relative/ friend's rights to access, change or move their information are limited, as the Sponsor organisation need to manage their information in specific ways in order for the research to be reliable and accurate. To safeguard your relative / friends rights, we will use the minimum personally-identifiable information possible.

You can find out more about how the Sponsor uses your relative / friends information using the information below:

- For Cambridge University Hospitals NHS Foundation Trust, please visit: https://www.cuh.nhs.uk/corporate-information/about-us/our-responsibilities/looking-after-your-information, or email the Data Protection Officer at: gdpr.enquiries@addenbrookes.nhs.uk

Cambridge University Hospitals will collect your relative / friend's name and contact details to contact them about this trial, and make sure that relevant information about the trial is recorded for their care, and to oversee the quality of the trial. Individuals from the Sponsor and regulatory organisations may look at their research records to check the accuracy of this trial. Cambridge University Hospitals will pass these details to the Sponsor along with the information collected from your relative / friend. The only people in the Sponsor organisation who will have access to information that identifies your relative / friend will be people who need to contact them in relation to this trial and to audit the data collection process. Cambridge University Hospitals will keep identifiable information about your relative / friend from this trial for 5 years after the trial has finished.

For participants recruited at other participating sites:
(Add site name) will keep your relative / friend's name, (NHS number) and contact details to contact them about this trial, and make sure that relevant information about the trial is recorded for their care, and to oversee the quality of the trial. Certain individuals from the Sponsor(s) and regulatory organisations may look at their medical and research records to check the accuracy of this trial. The Sponsor will only receive information without any identifying information.
(Add site name) will keep identifiable information about your relative / friend from this study for ## years after the study has finished.

All information collected about your relative / friend as a result of their participation in the trial will be kept strictly confidential. Their personal and medical information will be kept in a secured file and be treated in the strictest confidence.

Once you have agreed for your relative / friend to participate in this trial they will be allocated a Trial ID Number. This is a unique trial number which will be used on all their trial documentation along with their date of birth. Their date of birth is considered to be personal information. We collect this personal information on trial documentation to help ensure that the data we receive as part of their trial participation is correctly allocated to them. By cross checking these two unique references we can ensure the integrity of the data.

The people who analyse the information will not be able to identify your relative / friend and will not be able to find out their name, or contact details. Only anonymous trial data, without any personal information will be published at the end of the trial.

When you agree for your relative / friend to take part in this trial, the information about their health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Their information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify your relative / friend and will not be combined with other information in a way that could identify them. The information will only be used for the purpose of health and care research and cannot be used to contact your relative / friend or to affect their care. It will not be used to make decisions about future services available to them, such as insurance. If they have taken part in a parallel biomarker COVID-19 study at their hospital, we may wish to exchange information from the TACTIC-E trial with these study doctors to further enhance our knowledge of how the immune system handles COVID-19 and responds to different treatments. All your relative / friend's details will be anonymised.

We will need to inform your relative / friend's GP of their participation in this trial so that any medical decisions made by their GP account for any treatment they are receiving as part of this trial. Your relative/friend's GP may also contact us if they have any concerns about their participation in this study.

19. What will happen to your relative / friend's samples?

Blood and serum samples that are collected in this trial will be securely stored for the duration of the trial and will be accessible to authorised trial staff only. All trial samples will be labelled with Trial ID and date of birth. During the trial we will analyse your relative / friend's samples in a local laboratory though some may be analysed centrally in a Cambridge University Hospitals NHS Foundation Trust laboratory. With your permission any unused samples at the end of this trial will be stored at Cambridge University Hospitals NHS Foundation Trust for future tests related to this study, and for future approved research projects.

20. Genetic Tests

As part of the study, we may extract DNA from your relative / friend's sample. DNA is the chemical that makes up genes, influencing the factors we inherit and which determine our characteristics. We will also isolate and test other components of their blood such as RNA and protein and measure chemicals in the blood. We hope the results of this profiling will help us understand COVID-19 better. As this research is exploratory, your relative / friend will not receive feedback regarding any 'markers' identified in their DNA.

21. What will happen to the results of the trial?

The results of the trial will be anonymous and your relative / friend will not be able to be identified from any of the data produced. When the results of this trial are available, they may be published in peer reviewed medical journals and used for medical presentations and conferences. They will also be published on the EU Clinical Trials Register website, a central registry for all clinical trials conducted in the EU.

Coded datasets from the trial may also be made available to other researchers in line with national and international data transparency initiatives. These researchers may be outside

the European Union and EEA zone where privacy laws may not be as stringent – however, none of your relative/friend's personal details will be sent outside the EU. If your relative / friend would like to obtain a copy of the published results, please contact the trial doctor directly who will be able to arrange this for them.

22. Who is funding the trial?

The trial is being funded by AstraZeneca and Evelo Biosciences Ltd.

23. Who has reviewed this trial?

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your relative / friend's interests. This trial has been reviewed and given favourable opinion by (name of REC here). The Medicines and Healthcare Products Regulatory Agency (MHRA) who are responsible for regulating medicines in the UK have also reviewed this trial.

24. Further information and contact details

If you have any questions or require any further information about the trial, please feel free to contact:

*Study Doctor name: telephone: **********email: **********
Study nurse/coordinator name: telephone: ********** email: **********
****

In the event of an emergency please contact:

List 24 hour emergency contact detail here – this must match the information provided on the patient ID card and will be used to test the out of hours procedure for the trial.

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INFORMED CONSENT FORM

Trial Title: mulTi-Arm Therapeutic study in pre-ICu patients admitted with Covid-19 – Experimental drugs and mechanisms (TACTIC-E)

Principal Investigator: **Participant Number: _____**

If you agree with each sentence below, please initial the box

		INITIALS
1	I have read and understood the Information Sheet for Next of Kin/Personal Legal Representative version 1.0, dated 03 June 2020 for the above trial and I confirm that the trial procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that my relative / friend's participation in this trial is voluntary and that I am free to withdraw them at any time, without giving a reason and without their medical care or legal rights being affected.	
3	I understand that personal information about my relative / friend will be collected and used in accordance with this information sheet. This information will be kept in the strictest confidence and none of their personal data will be published.	
4	I understand that my relative / friend's GP will be informed of their participation in this trial	
5	I understand that my relative / friend may not receive the results from COVID-19 test/s taken as part of this trial.	
6	I understand that the doctors in charge of this trial may close the trial, or stop my relative / friend's participation in it at any time without their consent.	
7	I agree that my relative / friend may provide blood samples for research related to this trial, stored for up to 5 years and their samples may be transferred centrally for future analysis.	
8	I agree that DNA (genetic material) will be isolated from my relative /friend's donated blood sample and analysed through the use of advanced laboratory techniques.	
9.	I understand that coded trial datasets may be shared with researchers who may be based within or outside the European Union and European Economic Area.	
10	I agree that the patient I represent will participate in this study	

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INFORMED CONSENT FORM

Trial Title: mulTi-Arm Therapeutic study in pre-ICu patients admitted with Covid-19 – Experimental drugs and mechanisms (TACTIC-E)

Principal Investigator: **Participant Number: _____**

OPTIONAL

		YES	**NO**
9	I am happy for my relative / friend to be contacted in the future about further trials or extensions to this trial.		
10	I am happy for my relative / friend's information to be exchanged with other study teams where they have also been involved in a COVID-19 biomarker study		

Time of Consent (24hr clock) _____:_____

Name of person to participate in this trial: ……

…… ……. ……../……../…….
PRINTED name of Signature Date
Next of Kin / Legal Representative

…… Relationship to participant

…… ……. ……../……../…….
PRINTED name of Signature Date
person taking consent

1 copy for the NoK/PLR 1 copy for the trial team, 1 copy to be retained in the hospital notes