

REMAP-CAP

Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community-Acquired Pneumonia for COVID-19



Investigator: **Matt Wise**

Personal Legal Representative Information Sheet - Overview

Your relative / friend is invited to take part in the REMAP-CAP research study. This is because your relative / friend is unwell possibly or known to be due to a new coronavirus, COVID-19. This virus causes pneumonia (lung infection) and other illnesses, and is an important health problem.

We are continuing to test different treatments that may be beneficial for patients to ensure we provide the best possible treatment for your relative / friend. In this information sheet we have listed each treatment available at your hospital, including any potential benefits and risks. If you feel your relative / friend would wish to participate, they will be allocated by chance (called randomised) to at least one of these treatment options, but you and we will not know which treatment choice they will receive before this.

Before you decide whether your relative / friend would wish to take part, it is important for you to understand why the research is being done and what it will involve. This sheet tells you the purpose of this study, what will happen to your relative / friend and provides more detailed information about how the study will be carried out. Ask us if there is anything that is not clear or if you would like more information and discuss it with others if you wish.

If you do not think your relative / friend would wish to be part of this study, no further information will be collected about your relative / friend for the trial and the doctors will continue to provide them with whatever medical treatment is needed. Thank you for reading this.

Important things to know

- Your relative / friend has been admitted to hospital with COVID-19 and it is important to treat them as soon as possible
- COVID-19 is a new disease and we need to know which treatments are best
- Your relative / friend may be eligible to receive a number of different treatments
- These treatments will be randomly chosen for your relative / friend by a computer system (by chance)
- All treatments and a list of their possible benefits and risks are included in this information sheet
- All Your relative / friend's data will be kept confidential
- We will follow up with Your relative / friend in 6 months and ask them to complete a questionnaire
- Your relative / friend can withdraw from this study at any time and they will continue to receive the local standard treatments and care

1 copy for patient; 1 copy for Principal Investigator; 1 copy to be kept with hospital notes

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Information about the research

What is the purpose of the study?

The treatment for patients with pneumonia and other severe infections is generally based on national and international guidelines that guide healthcare professionals to choose the best treatments from the evidence available. As COVID-19 is a new disease it is not clear what the right treatments are. Treatment guidelines and recommendations from the World Health Organisation are that, for COVID-19, treatments with unknown benefit should only be given in a clinical trial.

The aim of this study is to investigate which of these treatment options are best for patients admitted to hospital or the intensive care unit (ICU) with suspected or confirmed COVID-19 infection.

What medical treatments are being investigated?

In this study, several different treatments are being compared at the same time. These treatments, which are available at your hospital, for COVID-19 can be put into the following different groups:

If Your relative / friend is being treated in the intensive care unit (ICU):

- 1) antiviral medication;
- 2) immune modulation;
- 5) immunoglobulin therapies;
- 6) Vitamin C Therapy;
- 7) Simvastatin Therapy;
- 8) Anticoagulation therapies, and
- 9) Antiplatelet Therapy

Why have I been chosen?

You have been asked to take part in this study as your relative / friend has been admitted to hospital or ICU due to known or suspected COVID-19. We know that treating patients early in this situation provides the best opportunity for medications to work well and so we need to include patients as soon as possible after they become unwell. We are planning to study about 1000 patients in total, admitted to different hospitals within the UK. We are also working closely with research partners internationally.

What does participation in this research involve?

It is up to you to decide whether your relative / friend would wish to take part in this study. If you do decide that your relative / friend would wish to take part, you will be given this information sheet to keep and be asked to sign a consent form. Your relative / friend is still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part at all, will not affect the standard of care your relative / friend receives.

This is a randomised study. Randomisation is a process that can be compared to tossing a coin. Sometimes we need to make comparisons to see which way of treating patients is the best. People are put into groups by chance and then compared. The groups are selected by a computer which has no information about the individual – i.e. so patients are put into the groups by chance. Each group has a different treatment and these are compared.

Additionally, this study is an 'adaptive' study. This means that the chances of being assigned to any of the treatment options may change on the basis of the study results, in favour of the most promising treatment. Neither you nor Your relative / friend's doctors will be informed of these changes in randomisation. This study assesses multiple different types of treatment. Your relative / friend may be eligible for all of them or

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only some of them, depending on their individual clinical condition. It is important for the treatment of Your relative / friend's pneumonia that the treatments are started as quickly as possible. This is why these treatments may have already be assigned ('randomized') to Your relative / friend when they were admitted to hospital or ICU. The doctor or researcher will explain the study and ask for your consent for Your relative / friend participation. If you do not think that your relative / friend would wish to participate in the study, no further data will be collected from them. The treatment that was previously started will be continued or will be changed if their doctor thinks this is necessary.

If you do consent for your relative / friend to participate in the study, they will continue to be treated with the treatments already started. Various routine data collected from your relative / friend throughout their hospital stay as part of routine care will be used for the study. If the doctors feel that their condition changes they can change their treatments as necessary.

What do I have to do?

You do not need to do anything for the study. A researcher will collect data from your relative / friend for the study, and you / your relative / friend will not notice anything. The data collected for the study are already collected as part of your relative / friend's daily and ongoing medical care. With your permission, we will also use routinely collected data held by either the Case Mix Programme, the national clinical audit of UK critical care units, run by the Intensive Care National Audit & Research Centre (ICNARC) or by NHS Digital. These data will include information regarding your relative / friend's health that will be important to answer the objectives of the study and will include, data from this and future hospital stays and survival data. We would also like to contact your relative / friend in 6 months' time with a short telephone call to ask about their quality of life and wellbeing.

If you do not think your relative / friend would wish to be part of this study, no further information will be collected about them for the trial and the doctors will continue to provide them with whatever medical treatment is needed.

What are the possible advantages and disadvantages of participating in this study?

The treatments that we are testing for COVID-19 are used to treat other viruses and other immune-related diseases but we do not know if they work well for the new COVID-19 disease. They may offer benefit and improve survival but could also harm. This study will tell us if some treatments are better than others but we cannot guarantee that taking part in this study will benefit your relative / friend directly but it will help improve treatment for people with COVID-19 in the future.

All medical treatments can cause side effects. The risks from side effects are similar if you choose for your relative / friend not to be in the study. Your relative / friend's doctor will know what treatment they are receiving at all times, and so the doctors will be looking out for any side effects.

What if something goes wrong?

University Medical Center Utrecht (UMCU) (The trial sponsor) holds insurance policies which apply to this study. If in the unlikely event your relative / friend experience serious and enduring harm or injury as a result of taking part in this study, they may be eligible to claim compensation without having to prove that UMCU is at fault. This does not affect your relative / friend legal rights to seek compensation. If your relative / friend is harmed due to someone's negligence, then they may have grounds for a legal action.

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If you wish to complain, or have any concerns about any aspect of the way your relative / friend has been treated during the course of this study then you should immediately inform the local Investigator (Dr Wise, contact details at end). The normal National Health Service complaints mechanisms are also available to you.

Will information from this study be kept confidential?

Yes. This is a large global trial and we will follow the law by making sure your relative / friend's information is kept private and secure. UMC Utrecht is the sponsor for this study based in the Netherlands. We will be using information from your relative / friend's medical records in order to undertake this study and UMC Utrecht will act as the data controller for this study. This means that they are responsible for looking after your relative / friend information and using it properly. UMC Utrecht will be storing de-identified study data on servers based in Sydney Australia. This information will be kept for 15 years after the study has finished.

Your relative / friend's rights to access, change or move their information are limited, as we need to manage their information in specific ways in order for the research to be reliable and accurate. If your relative / friend withdraws from the study, we will keep the information about them that we have already obtained. To safeguard your relative / friend's rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your relative / friend's information by contacting privacy@umcutrecht.nl.

Cardiff and Vale UHB will collect information from your relative / friend's medical records for this research study in accordance with the sponsor's instructions.

Cardiff and Vale UHB will keep your relative / friend's name, NHS number and contact details confidential and will not pass this information to UMC Utrecht. **Cardiff and Vale UHB** will use this information as needed, to contact your relative / friend about the research study, and make sure that relevant information about the study is recorded for their care, and to oversee the quality of the study. Certain individuals from UMC Utrecht and regulatory organisations may look at your relative / friend's medical and research records to check the accuracy of the research study. UMC Utrecht will only receive information without any identifying information. 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, NHS number or contact details.

Minimal randomisation and clinical data will be collected on servers in Sydney Australia which will collect some personal information about your relative / friend for this global study. This information will include their initials, date of birth and gender and basic eligibility health information. The information will be held securely with strict arrangements about who can access the information. With your permission, in order that we can contact your relative / friend in 6 months and identify them in the Case Mix Programme database (as outlined above) this hospital will provide your relative / friend's name, telephone number and NHS number to ICNARC (based in the UK), alongside some additional clinical data. Once your relative / friend has been identified, the trial team will share their postcode, date of birth and NHS number (held by the Case Mix Programme), along with their name with NHS Digital. This will enable NHS Digital to provide us with information as described above.

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Cardiff and Vale UHB will keep identifiable information about your relative / friend from this study for 15 years after the study has finished. When you agree for your relative / friend to take part in a research study, 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. Your relative / friend's 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 your relative / friend, such as insurance. It is necessary for us to process our relative / friend's data as described to allow us to perform a task in the public interest (lawful basis).

What will happen to the results of the research study?

The study stops for your relative / friend once they have completed their 6 month follow up telephone conversation with a member of the clinical research team. Your relative / friend will not be personally informed about the results of the study. The results of this study will be presented at medical meetings and published in scientific journals. Only anonymous group information and no personal information will be presented. If you are interested in the results you will be able to look them up after the trial has finished. The website link where you can see the overall results will be: www.remapcap.org.

Who is organising and funding the research?

The Coordinating Principal Investigator for this study is Professor Marc Bonten, at the University Medical Center Utrecht, Netherlands. This research has received funding from the EU FP7-HEALTH-2013 INNOVATION-1 Grant as part of the global PREPARE consortium. The cost of some treatments for immune modulation for COVID-19 may be covered by pharmaceutical companies that make these products. These pharmaceutical companies have no involvement in the design, analysis, or reporting of results from the trial. The UK Principal Investigator is Professor Anthony Gordon at Imperial College London, and the UK Trial Coordinating Centre is ICNARC, Napier House, 24 High Holborn, London WC1V 6AZ.

Who has reviewed the study?

All research involving patients in the NHS is looked at by an independent group of people called a Research Ethics Committee. This study has been reviewed and approved by the **London- Surrey Borders HRA Ethics Committee**.

Who can I contact for independent research information?

If you have any questions about being in a research study, you can contact the Trust's Patient Advice Liaison Service (PALS). They will give you advice about who you can talk to for independent advice.

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Local PALS office telephone number	Local PALS office address
02920 744095 concerns@wales.nhs.uk	Concerns Team University Hospital of Wales Cardiff CF14 4XW

Further information

Thank you for considering your relative / friend participation in this study. If you have any questions about this research, the local study staff will be more than happy to answer them. Their contact details are:

Study Investigators Contact details

Study Investigator	Dr Matt Wise
Study Nurse	Critical Care Research Team
Day time Telephone	02920743608
Emergency Telephone	02920746800

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CONSENT FORM FOR PATIENTS UNABLE TO GIVE CONSENT (Hospital level)

Patient Study ID		Site #	
Name of Research Doctor			

Please initial each box if you agree with the following:

I, (forename and surname)..... freely agree for my relative / friend to take part in the study.

- I confirm that I have read and understood the participant information sheet dated 1st October 2020 v1.7 for the above study and have been able to ask questions which have been answered fully.
- I agree for my relative / friend to take part in the therapeutic anticoagulation domain
- I agree for my relative / friend to take part in the antiplatelet domain
- I understand that my relative / friend's participation is voluntary and they are free to withdraw at any time, without giving any reason and without their medical care or legal rights being affected.
- I understand my relative / friend's identity will never be disclosed to any third parties and any information collected will remain confidential.
- I agree that my relative / friend's medical records and other personal data generated during the study may be examined by representatives of the sponsor (UMC Utrecht), by people working on behalf of the sponsor, and by representatives of Regulatory authorities, ICNARC and NHS Digital where it is relevant to my taking part in this research.
- I agree that I will not seek to restrict the use to which the results of the study may be put.
- I understand my relative / friend's will be contacted by ICNARC in six months to ask about their quality of life and wellbeing. *[delete if not taking part in follow-up aspect]*
- I understand that minimal randomisation data collected about my relative / friend will be transferred outside of the EEA.
- I understand that my relative / friend's consent will override my consent when they are able to provide informed consent

<p>Personal Legal Representative</p> <p>Date:</p> <p>Signature:</p> <p>Printed Name:</p>	<p>Person responsible for collecting the informed consent</p> <p>Date:</p> <p>Signature:</p> <p>Printed Name:</p>
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Witness Consent (in the event the patient cannot sign) Date: Signature: Printed Name:	
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Treatments available at this ICU

1. Use of COVID-19 antiviral medication. When a patient has known or suspected COVID-, some doctors will prescribe antiviral medications. These antiviral medications work in other situations, but we don't know if any of them work against COVID-19 or not. At this site, this study evaluates:

- Lopinavir/ritonavir (also known as Kaletra)
- No antiviral medication intended to be active against COVID-19

The doctors in this ICU have selected these options because they do not know which treatment option is best.

2. Use of COVID-19 immune modulation. There are some medicines that may work in COVID-19 disease by altering the patient's immune response to the virus. These drugs are used in other diseases to alter inflammation and the body's immune response but we don't know if any of them work in COVID-19. At this site, this study evaluates:

- Interferon-beta 1a
- Anakinra
- Tocilizumab
- Sarilumab
- No agent that is intended to modulate the immune response

The doctors in this ICU have chosen these options because they don't know which option is best.

5a. Use of COVID-19 Immunoglobulin Therapy (standard sampling) COVID-19 immunoglobulin therapy is a blood-based treatment, giving patients antibodies to help fight infection. Antibodies are found in plasma, which is the liquid part of blood. It contains a mixture of proteins including antibodies, clotting factors, and natural anticoagulants. Convalescent plasma is plasma collected from volunteers who have recovered from COVID-19, which contains antibodies to help fight COVID-19. At this site the study evaluates:

- No Immunoglobulin Therapy
- Convalescent Plasma

Convalescent plasma has been used to treat other viruses in the past but doctors are unsure if giving it to people with COVID-19 will be beneficial. Part of this study includes taking additional blood and respiratory samples when your relative / friend enters the study, the blood sample will take 6mls (just over 1 teaspoon) of blood. These samples will be transported to a central laboratory for testing. All samples

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collected from your relative / friend under this study will be used within this study or in other ethically approved studies.

Your relative / friend will only receive these treatments if they have pneumonia that is believed or known to be caused by the Coronavirus.

6. Vitamin C therapy. It has been suggested that high doses of vitamin C may be useful to treat infection and the inflammation often seen in sepsis and especially COVID-19. However, there is no clear evidence of benefit for this treatment yet.

The following interventions will be available:

- No vitamin C (no placebo)
- Intravenous Vitamin C for 4 days

7. Simvastatin therapy. Statins are commonly used to lower cholesterol and lower the risks of heart attacks or strokes. One of these drugs, simvastatin has also been shown to reduce inflammation and therefore may be beneficial to treat COVID-19.

The following interventions will be available:

- No simvastatin (no placebo)
- Simvastatin

8. Anticoagulation therapy – ICU level. All critically ill patients are at risk of developing blood clots in their legs that can move to the lungs and cause severe breathing problems. It is usual to give small doses of blood “thinners” (heparin drugs) to try and prevent these clots. Patients with COVID-19 appear to be at even higher risk of developing blood clots. Therefore, patients may require higher doses of these drugs to “thin” the blood even more. But this could increase the risk of bleeding and therefore doctors are uncertain which strategy is best. At this site, this study evaluates:

- Standard low dose (prophylactic / preventative) heparin
- Treatment (higher) dose heparin

9. Antiplatelet Therapy.

Blood clots that develop in arteries are common in hospitalised patients with COVID-19 and antiplatelet therapy is commonly used in treating this. These drugs have been shown to prevent the development in blood clots and inflammation and therefore may be beneficial in the treatment of COVID-19

The following interventions will be available:

- No antiplatelet (no placebo)
- Aspirin
- P2Y12 inhibitor (Clopidogrel, Prasugrel or Ticagrelor)

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Possible side effects

Different types of antibiotics are used as part of the study. These medications are used as part of normal care, and the side effects are minimal, but these drugs can still give side effects. The antibiotics and antivirals used as part of this study may have the following side effects:

Diarrhoea, dizziness, headache, stomach ache, tingling sensations, nausea, vomiting, heartburn, unpleasant taste, inflammation of the mouth and the tongue, deteriorating vision, deafness, loss of appetite, low blood sugar, itching, skin rash, joint pain, fatigue, vein inflammation, general anaemia, cardiac arrhythmia, excessive sweating, shortness of breath, sleepiness, anxiety and confusion, and nervousness.

These side-effects are similar for most different antibiotics and antivirals.

Immune modulators may have the following side effects:

Headache, runny nose, vomiting, diarrhoea, nausea, rash, fever, chills, fatigue, night sweats, bruising, muscle cramp, muscle and joint pain/stiffness, injection site reactions (e.g. bruising/pain), increased blood cholesterol level, decrease in white blood cells and/or platelets, changes in liver function tests, muscle stiffness, numbness of the skin, and increased risk of infection.

Convalescent plasma has been used to treat other viral infections, but its effects are not known in people with COVID-19. However, the risk that a standard plasma transfusion may make your relative / friend ill is very low. A plasma transfusion may have the following side-effects:

Allergic reactions (rash, fever, chills) or increased difficulty breathing. These reactions are usually mild and are easily treated with medicines such as paracetamol and antihistamines, or by slowing down or stopping the plasma transfusion.

Vitamin C may potentially cause kidney stones.

Simvastatin is a medicine used to lower cholesterol and the risks of heart attacks or strokes and may have the following side effects:

Muscle aches, pains, tenderness or weakness, and temporary changes in liver blood tests.

Heparin is a blood thinner that can prevent and treat blood clots but it can also increase the risk of bleeding. This can be minor, e.g. bruising, but sometimes can be more severe, e.g. require a blood transfusion.

Aspirin is commonly used to treat pain, fever and inflammation. Common side effects are nausea, vomiting or stomach pain. Common side effects of P2Y12 inhibitors are stomach pain, bleeding, dizziness and chest pain.

Other rare side effects may occur (in less than 1% of people) but the doctors and nurses looking after your relative / friend will watch carefully for these possible effects and treat them as necessary and even stop the treatment if needed.

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CONSENT FORM FOR PATIENTS UNABLE TO GIVE CONSENT (ICU)

Patient Study ID		Site #	
Name of Research Doctor			

Please initial each box if you agree with the following:

I, (forename and surname)..... freely agree for my relative / friend to take part in the study.

- I confirm that I have read and understood the participant information sheet dated 1st October 2020 v1.7 for the above study and have been able to ask questions which have been answered fully.
- I agree for my relative / friend to take part in the COVID-19 antiviral domain. *[delete if not taking part in COVID-19 antiviral treatment domain]*
- I agree for my relative / friend to take part in the COVID-19 immune modulation domain. *[delete if not taking part in COVID-19 immune modulation treatment domain]*
- I agree for my relative / friend to take part in the antibiotic domain. *[delete if not taking part in antibiotic treatment domain]*
- I agree for my relative / friend to take part in the macrolide domain. *[delete if not taking part in macrolide treatment domain]*
- I agree for my relative / friend to take part in the immunoglobulin therapy domain. *[delete if not taking part in immunoglobulin therapy domain]*
- I agree that for my relative / friend blood and respiratory samples can be retained by researchers as part of the study. *[delete if not taking part in immunoglobulin therapy domain]*
- I agree that these samples can be donated as a gift to researchers for future research purposes. *[delete if not taking part in immunoglobulin therapy domain]*
- I agree that DNA and RNA from my relative / friend's blood sample will be analysed to determine whether any genetic factors have made my friend / relative susceptible to severe infection. *[delete if not taking part in immunoglobulin therapy domain]*
- I agree for my relative / friend to take part in the therapeutic anticoagulation domain *[delete if not taking part in therapeutic anticoagulation domain]*
- I agree for my relative / friend to take part in the Vitamin C domain *[delete if not taking part in Vitamin C domain]*
- I agree for my relative / friend to take part in the Simvastatin domain *[delete if not taking part in Simvastatin domain]*
- I agree for my relative / friend to take part in the Antiplatelet domain *[delete if not taking part in Antiplatelet domain]*

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- I understand my relative / friend's identity will never be disclosed to any third parties and any information collected will remain confidential.
- I agree that my relative / friend's medical records and other personal data generated during the study may be examined by representatives of the sponsor (UMC Utrecht), by people working on behalf of the sponsor, and by representatives of Regulatory authorities, ICNARC and NHS Digital where it is relevant to my relative / friend taking part in this research.
- I agree that I will not seek to restrict the use to which the results of the study may be put.
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- I understand that my relative / friend's consent will override my consent when they are able to provide informed consent

Personal Legal Representative

Date:

Signature:

Printed Name:

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