**REMAP-CAP**

**Patient Information Summary and Consent Form**

**For patients with capacity or now recovered capacity**

**What is it?**

A respiratory tract infection (an infection that affects the nose, throat, airways or lungs) such as pneumonia can be caused by bacteria or viruses like flu (influenza) and COVID-19. When a patient becomes ill because of this, there are several types of treatments that may help them recover. REMAP-CAP is a clinical trial designed to understand the best treatment options for this type of infection.

**What are the treatments?**

We are testing various treatments both on the ward and in the ICU.

Antibiotics:

[ ] We are not taking part at this hospital

The following are being compared (only those in bold): ceftriaxone and a macrolide, piperacillin-tazobactam and a macrolide, amoxicillin-clavulanate and a macrolide, moxifloxacin or levofloxacin.

Macrolides:

[ ] We are not taking part at this hospital

The following are being compared (only those in bold): azithromycin, clarithromycin, or roxithromycin.

Corticosteroids:

[ ] We are not taking part at this hospital

The following are being compared (only those in bold): dexamethasone (for up to 10 days), hydrocortisone (if you have septic shock, which is when your infection is causing organ failure), or no corticosteroids.

Influenza (flu) antivirals:

[ ] We are not taking part at this hospital

The following are being compared (only those in bold): oseltamivir (a short or long course), baloxavir, the combination of both oseltamivir and baloxavir, or no antiviral.

Immune modulators:

[ ] We are not taking part at this hospital

The following are being compared (only those in bold): baricitinib, tocilizumab, or no immune modulator.

Immunoglobulin therapy:

[ ] We are not taking part at this hospital

[ ] We are comparing convalescent plasma with no convalescent plasma treatment.

*(please bolden treatment(s) that the site IS participating in, and/or tick as appropriate, in the text above)*

Your doctor will know which set of treatments are suited to you in the study. We may use a combination of these treatments because it is important to understand which combinations are best. Many of these treatment comparisons also include a ‘no additional treatment’ option, so you may not receive any of these treatments, but you will still receive the standard of care at the hospital.

**Will all treatments be offered to the patient?**

Your hospital can select which treatments they would like to participate in. You will be randomised to all treatment options available at this hospital. REMAP-CAP is a randomised trial which ensures that balanced groups are compared, and this allows us to understand which way is best to treat patients. The study looks at the results on an ongoing basis and uses these results to make some changes to the randomisation process with the aim of increasing the chances of getting treatments that are looking better for new patients in the study, but there is no guarantee.

As this is an emergency situation, treatment should be started as quickly as possible, and you will be updated by the clinical team as soon as it is practical. This summary can be used to provide some simple information. An information sheet with the full details is also available from the doctor, nurse, or researcher should you wish to read it. All conversations will be documented in your medical records. If you decide that you do not want to take part, your choice will be respected. No further information will be collected about you, and this will not affect the standard of care that you receive.

**Informational video**

Please feel free to watch a short video that summarises the study by scanning the QR code below with your phone’s camera:

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**CONSENT FORM FOR PATIENTS ABLE TO GIVE CONSENT**

**(FOR PATIENTS WITH CAPACITY)**

**REMAP-CAP**

|  |  |  |  |
| --- | --- | --- | --- |
| **Patient Study ID**  |  | **Site #** | *(add number/name)* |
| **Patient Name** |  |
| **Name of Principal Investigator****(use CAPITALS)** | *(add)* |

**Please initial each box if you agree with the following:**

I, *(forename and surname)*………………………………………………………………………………………………, freely agree to take part in the study.

|  |  |
| --- | --- |
|  | 1. I confirm that I have read (or had read to me) and understood this document and have read/received a copy of the appropriate information sheet for the above study and have been able to ask questions which have been answered fully. |
|  | 2. I give consent to take part in the following domains: **antibiotics, macrolides, corticosteroids, influenza (flu) antivirals, immune modulators, or immunoglobulin therapy***(delete domains site is not participating in)**(strikethrough domain(s) if the representative does not agree)* |
|  | 3. I understand that I can choose to take part, and I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected.  |
|  | 4. I understand that my identity will never be given to any third parties, and any information collected will remain confidential. |
|  | 5. I understand that my medical records and other personal data generated during the study may be looked at 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. |
|  | 6. I agree that I will allow the researchers to decide how to use the results of this study. |
|  | 7. I understand that I will be contacted by ICNARC or the local hospital in six months to answer questions about my quality of life and wellbeing.  |
|  | 8. I understand that minimal randomisation data collected about me will be transferred outside of the EEA where the privacy rules of the European Union do not apply. I understand that an equivalent level of protection will be ensured for my data.*(Note: if this point is refused the patient cannot be included in the trial)* |
|  | 10. I give consent for blood samples/nose swabs collected from me to be used to support other research or in the development of a new test, medication, or treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which the sponsor - UMC Utrecht - has ensured to keep secure). |

Patient’s name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_                                  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Consent** date (dd/mmm/yyyy):        /        /           Time:       :       (24hr)

**To be completed by the impartial witness\*** *in the event the patient is competent but unable to read, or unable to sign or date the informed consent form.*

**I confirm that the patient information and informed consent have been accurately explained to the patient, the informed consent has been apparently understood by the patient, and the patient has voluntarily agreed to consent to participate in the study.**

Impartial witness’ name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*\*An impartial witness is independent of the study, who cannot be unfairly influenced by people involved with the study (e.g., an independent nurse or a patient visitor)*

Date (dd/mmm/yyyy):       /       /       Time: : (24hr)

**To be completed by the delegated site staff obtaining consent**

I hereby declare that I have provided complete and accurate information about the study, and I have answered all questions.

If new information becomes known during the study that could affect the consent for participation, I will inform the patient in good time.

Investigator name (or delegate): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date (dd/mmm/yyyy):        /        /

*1 original copy for ISF; 1 copy for participant; 1 copy for hospital notes*

*To ensure confidence in the process and minimise risk of loss, all consent forms must be printed, presented, and stored in double sided format*