**REMAP-CAP**

**Professional Legal Representative Summary and Consent Form**

**What is it?**

REMAP-CAP is a clinical trial designed to understand the best treatment options for COVID-19, influenza, or other pneumonia. When a patient becomes ill because of these conditions there are several types of drugs that may help them recover. REMAP-CAP has been designed to test different types of drugs and the various combinations of these treatments.

**What are the treatments?**

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

The treatments for COVID-19 are: - low or a middle dose heparin, cysteamine, immunoglobulin therapy, antibiotics (ceftriaxone, piperacillin-tazobactam, amoxicillin-clavulanate, moxifloxacin or levofloxacin), with macrolides (azithromycin, clarithromycin, or erythromycin), or no treatment.

The treatments for flu are: - oseltamivir, baloxavir, dexamethasone, hydrocortisone, tocilizumab, baricitinib, or no treatment.

The treatments for other pneumonia are: - cysteamine, dexamethasone, hydrocortisone, antibiotics (ceftriaxone, piperacillin-tazobactam, amoxicillin-clavulanate, moxifloxacin or levofloxacin), with macrolides (azithromycin, clarithromycin, or erythromycin), or no treatment.

Patients in this study may be treated with any combination of these drugs because it is important to understand what the best combination of treatments is. Many of the treatment options listed above also include a ‘no treatment’ option and so the patient may not receive any of these treatments if they choose to participate.

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

Your hospital can select which treatments they would like to participate in. The patient will be randomised to all treatment options available at site. REMAP-CAP is a randomised trial so that balanced groups are compared, and this allows us to understand which way is best to treat patients. Additionally, this study uses adaptive randomisation. This means that the chances of being assigned to any of the treatment options may change based on the study results, in favour of the most promising treatment.

**Current findings**

Due to our ‘adaptive’ model we can evaluate treatment options quickly and have so far discovered that the use of hydrocortisone reduces the need for organ support in patients with COVID-19. We also demonstrated that the immune modulators tocilizumab and sarilumab both improve outcomes in critically ill patient with COVID-19. These interventions are now Standard of Care in ICUs in the UK.

As this is an emergency situation, treatment should be started as quickly as possible and may need to be started before we can speak to the patient or family members to seek formal consent. As soon as practical the patient or family & friends should be updated. This brief summary can be used to provide some simple information. Full detailed information sheets are also available. Please document all conversations with patients or next of kin in the patient’s notes. If patients do not want to take part that is their choice and should be respected and this will not affect the standard of care that they receive. Please document their wishes in the notes so that they do not get included in an emergency situation.

**Consent Form for Participants Unable to Give Consent Themselves**

**REMAP-CAP**

|  |  |  |  |
| --- | --- | --- | --- |
| **Patient Study ID** |  | **Site** |  |
| **Name of Principal Investigator** |  | | |

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

I, *(forename and surname)* ……………………………………………………………………………………………… consent for this patient to take part in the study.

|  |  |
| --- | --- |
|  | 1. I confirm that I have read and understand this document and have read/received a copy of the appropriate patient information sheet for the above study and have been able to ask questions which have been answered fully. |
|  | 2. I give consent for this patient to participate in the following domains: -  **cysteamine domain, immunoglobulin domain, influenza antiviral domain, steroid domain, immune modulation domain, antibiotic domain,** or **macrolide domain** (d*elete domains not participating in and strikethrough domain if ProLR does not agree)* |
|  | 3. I understand that I am giving this consent based on what I believe would be the person for whom I am providing consent’s wishes. In my opinion they would be willing to participate. |
|  | 4. I understand that sections of any of the patient’s medical notes may be looked at by responsible individuals’ 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 their taking part in this research. |
|  | 5. I consent that I believe the patient will not seek to restrict the use to which the results of the study may be put. |
|  | 6. I understand that the patient will be contacted by ICNARC or the local hospital in six months to ask about their quality of life and wellbeing. |
|  | 7. I understand that minimal randomisation data collected about the patient will be transferred outside of the EEA.  *(Note if this point is refused the patient cannot be included in the trial)* |
|  | 8. I understand that once the patient regains capacity this consent form no longer has merit, and the patient will be superseded by the patient’s informed consent. |

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Name of Professional Legal Signature Date

Representative

(*not listed on study delegation log*)

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Name of staff member Signature Date

*(Listed on study delegation log)*

1 copy for participant; 1 copy for Principal Investigator; 1 copy to be kept with 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