**REMAP-CAP**

**Information Sheet and Consent form**

**for parents/guardians/caregivers and young people aged 16 and 17 years old.**

***To be provided to young people who are aged 16 and 17 and are capable of giving their consent. If not to be provided to their parent/guardian/caregiver.***

**Invitation to the study**

We are inviting people of any age who have been admitted to hospital with pneumonia or influenza (flu), to participate in our research study. This study is trying to find treatments for this health problem. This form provides information about the study, the treatments we are using, and risks and benefits of taking part.

**Why are we running this study?**

Pneumonia (lung infection) and Influenza (flu) are both important current health problems. Current treatments for these are based on previous research that help doctors to choose the best care. There may be better treatments available, and it is up to us to find them. To do this more research is needed to see whether there are better and more effective treatments. The aim of this study is to find out which treatments are best for patients admitted to hospital with pneumonia or Influenza (flu).

**What treatments are we testing?**

The treatments we are testing are listed below. We are testing these in patients who have been admitted to the hospital.

The treatments are: - oseltamivir, baloxavir, (both antiviral medications), dexamethasone, ( steroid), tocilizumab, baricitinib (both immune modulators) or no treatment

*(please delete treatment if site not participating)*

Just to let you know that not all treatments may be available at your hospital, your doctor will be able to tell you which treatments are available and suited to you (or your child).

**Who will be included in the study?**

Patients who have been admitted to hospital who have or are suspected to have pneumonia or Influenza (flu). Only patients who meet the study criteria and are considered suitable by their treating doctor will be included. The treatments available depend on the seriousness of the condition and criteria of the study.

**What does participation in this study involve?**

* Participation is entirely your decision. If you decide that you (or your child) will take part, we will ask you to sign a consent form. Next, we will enter some details about you (or your child) and answer some medical questions on a computer.
* You (or your child) will then be randomised by a computer to one or more treatments. Randomisation is a process like tossing a coin and you (or your child) will be placed in a group by chance which allows us to compare your (or your child’s) group to others.
* Once you (or your child) have been randomised, depending on the treatment a nose swab sample will be taken, these will also be collected 3 and 7 days later.
* If you (or your child) are randomised to receive a treatment, you (or your child) may receive this by an injection or a tablet. The doctor or nurse will explain the study to you, but neither they nor you can decide on which treatment you (or your child) receive.
* Young women will also have a urine test for pregnancy as some treatments may not be suitable
* Further information about your (or your child’s) health will be entered on to a computer.
* Once you (or your child) leave hospital no further hospital visits are required.
* We will contact you 6 months after your (or your child’s) inclusion to complete a questionnaire about your (or your child’s) wellbeing. To ensure we can learn the effects of the study treatment we will collect information about you (or your child) from your medical records until 6 months after you agreed to participate.
* We will also request information about you (or your child) from some research databases: - Intensive Care National Health Audit & Research Centre (ICNARC), NHS Digital, UK Health Security Agency, genetic and other research databases (if you have provided information/samples to them). We will keep this information for up to 10 years after your/your child’s hospital stay. All your data that has been collected will be pseudonymised, which means that your (or your child’s) data will be allocated a reference number and so you (or your child) cannot be directly identified by this.
* You (or your child) can choose to withdraw from the study at any time, without giving any reasons.

**Are there any benefits in taking part?**

This study will tell us if some treatments are better than others, but we cannot guarantee that taking part in the study will benefit you/your child directly, but it may help improve treatment for people with pneumonia or influenza (flu) in the future. This study may also allow us to stop using treatments that do not work.

**Are there any risks in taking part?**

All medical treatments can cause side effects. The risks and side effects are similar whether you choose to be in the study or not. Your doctor will know what treatment you/your child are receiving at all times and so will be looking out for any side effects. We have listed the common side effects specific to our treatments below: -

* Antivirals (oseltamivir and baloxavir), may cause many mild side-effects such as headache, stomach-ache, nausea, vomiting, heartburn, itching, skin rash, joint pain, anxiety, and confusion.
* Steroids – dexamethasone may cause sleep problems, mood changes, indigestion, and weight gain.
* Immune modulators (tocilizumab or baricitinib) may cause blocked/runny nose, cough, sore throat, headache, and an increase in cholesterol.

**Pregnancy**

Women who are pregnant or breastfeeding may be included depending on the type of treatment. Some treatments have not been tested on pregnant women before e.g., baloxavir, baricitinib and the effect on unborn babies is uncertain. In such cases these treatments may not be available. As part of the study, we have an expert panel who review our safety results closely and if there are any issues, your (or your child’s) treatment will be stopped immediately.

**Can I stop/change my mind?**

Participation is up to you. If you no longer wish for you (or your child) to be part of this study, no further information will be collected about you (or your child) for the trial and the doctors will continue to provide you (or your child) with routine medical treatment. You will have the option to allow us to collect subsequent information about you (or your child). De-identified information about you that has already been collected up to the point that you (or your child) withdrew from the study will still be analysed by the study team.

**What if I have a problem or a question?**

If you have any questions about the study, please reach out to your (or your child’s) medical team in the first instance. Further information about the study can be found on our study website:

[www.icnarc.org/Our-Research/Studies/Remap-Cap/](http://www.icnarc.org/Our-Research/Studies/Remap-Cap/) via email ukremap-cap@icnarc.org or telephone: - 020 7594 5906. For independent research advice please see contact information below: -

***England/Wales sites only***

If you have any questions about you (or your child) 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.

|  |  |
| --- | --- |
| **Local PALS office telephone number**  | **Local PALS office address**  |
|   |   |

***Northern Ireland sites only***

If you have any questions about you (or your child) being in a research study, you can contact the person listed below. They will give you advice about who you can talk to for independent advice.

|  |  |
| --- | --- |
| Local Contact  | Local address  |
|   |   |

***Scotland sites only***

If you have any questions about you (or your child) being in a research study, you can contact [*insert full name*] (contact details below) who is not involved in the study and will be able to give you independent advice.

[*insert independent contact telephone number/email address/postal address*]

University Medical Center Utrecht (UMCU) (the trial sponsor) has insurance policies for this study. If in the unlikely event you/your child experience serious harm or injury as a result of taking part in this study, you (or your child) may be eligible to claim compensation without having to prove that it was UMCU’s fault. This does not affect your legal rights to seek compensation. If you (or your child) are harmed due to someone’s negligence, then you may have grounds for a legal action.

**How do you use information about me (or my child) and how to do you keep it private?**

All information about you (or your child) including health information and participation will be kept private. The only people who will have access to this information are your (or your child’s) doctors and nurses looking after you (or your child) and employees of the Sponsor UMC Utrecht, Imperial College London and ICNARC who have authorisation. More information is available in our privacy notice on our website <https://www.icnarc.org/Our-Research/Studies/Remap-Cap/About> or if you prefer you can ask for a copy from your medical team.

**How do I find out the results?**

You 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 group information and no personal information will be presented. If you are interested in the results, they will be available on our global website <https://www.remapcap.org/>

**Who is funding it?**

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 Rapid European COVID-19 Emergency Research response (RECOVER) consortium by the European Union’s Horizon 2020 research and innovation programme (#101003589) and from the UK National Institute for Health and Care Research (NIHR). The cost of some treatments may be covered by companies that make these products.  These companies have no involvement in the running of 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 and approved it?**

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.**

**CONSENT FORM FOR YOUNG PEOPLE AGED 16 TO 17 AND ARE CAPABLE AND/OR THEIR PARENT/GUARDIAN/CAREGIVER**

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

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

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

|  |  |
| --- | --- |
|  | 1. I confirm that I have read (or had read to me) the relevant patient information sheet for the above study and have been able to ask questions which have been answered fully. |
|  | 2. I agree for me (or my child) to take part in the following domains: - **antiviral domain, steroid domain,** and/or **immune modulation domain** (d*elete domains not participating in and strikethrough domain if patient does not agree)* |
|  | 3. I understand that my (or my child’s) participation is voluntary, 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 my (or my child’s) personal information will never be provided to any third parties and any information collected will remain private. |
|  | 5. I agree that my (or my child’s) medical records and other personal data generated during the study may be seen by authorised people of the sponsor (UMC Utrecht), and by people from of Regulatory authorities, ICNARC and NHS Digital for this research. |
|  | 6. I agree that I am happy for the researchers of this trial to decide how to publish the results. |
|  | 7. I understand I will be contacted by ICNARC or my local hospital in six months to ask about my/my child’s quality of life and wellbeing.  |
|  | 8. I understand that a small amount of randomisation data collected about me/my child will be transferred outside of the EEA. |

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Name of patient Signature Date

*If capable*

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Name of parent/guardian/ Signature Date

caregiver

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Name of staff member Signature Date

*(Listed on delegation log)*

*If the patient/parent/guardian/caregiver is* ***not able*** *to write/sign due to condition or weakness, please ensure a witness signs the section of the consent form below. The witness will be a member of the clinical team who is not part of the study team (not listed on the delegation log)*

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Name of witness Signature Date

*\*Independent of the REMAP-CAP study team*

1 copy for participant; 1 copy for Principal Investigator; 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