**REMAP-CAP**

**Information Sheet and Consent form**

**for parents/guardians/caregivers of younger children**

**Information for parents/guardians/caregivers**

**Invitation to the study**

We are inviting children and young people who have been admitted to hospital with pneumonia (lung infection) and influenza (flu) to participate in our research study. This study is trying to find treatments for this health problems. This form provides information on the study, the treatments we are using, and risks and benefits of taking part.

**What is the purpose of this study?**

Pneumonia and Influenza (flu) are both important current health problems. Current treatments for these are based on previous research used in international guidelines that help doctors to choose the best care. As new treatments become available more research is needed to see whether there are better and more effective treatments. The aim of this study is to investigate which treatments are best for patients admitted to hospital with pneumonia and influenza (flu).

**What treatments are being investigated?**

We are testing treatments in patients who have been admitted to the ward and / or the ICU.

The treatments for flu are: - oseltamivir, baloxavir, (both antiviral medications), dexamethasone, (steroid), tocilizumab, barcitinib (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 child’s hospital, your child’s doctor will be able to tell you which treatments are available and suited to your child.

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

Patients who have been admitted to hospital or to ICU who have or are suspected to have flu or pneumonia. Only patients who meet the study criteria and are considered suitable by their treating doctor will be included. The treatments available are dependent on the severity of the condition and eligibility criteria.

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

* Participation is entirely voluntary. If you agree for your child to participate, we will ask you to sign a consent form. Next, we will enter some details about your child and answer some medical questions on a computer.
* Your child will then be randomised by a computer to one or more treatments. Randomisation is a process like tossing a coin and your child will be placed in a group by chance which allows us to compare your child’s treatment 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 your child is randomised to receive a treatment they may receive this via an injection or a tablet. The doctor or researcher will explain the study to you and your child, but neither they nor you can decide on the treatment allocation.
* Further information about your child’s health will be entered on to a computer.
* Once your child is discharged from hospital no further visits are required by your child.
* We will contact you 6 months after your child’s inclusion to complete a questionnaire about their wellbeing. To ensure we can learn the effects of the study treatment we will collect information about your child from your medical records until 6 months after their inclusion; this includes information before and after their inclusion.
* We will also request information about your child from the following 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 your child’s information/samples to them). We will keep this information for up to 10 years after their discharge. All your child’s data that has been collected will be pseudonymised, which means that your child’s data will be allocated a reference number and so they cannot be directly identified by this.
* You can choose to withdraw your child 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 your child directly, but it may help improve treatment for people with flu, or pneumonia in the future. This study may also allow us to stop using treatments that do no 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 for your child to be in the study or not. Your child’s doctor will know what treatment they 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.

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

Participation is voluntary. If you no longer wish for your child to be part of this study, no further information will be collected about them for the trial and the doctors will continue to provide your child with routine medical treatment. You will have the option to allow us to collect subsequent information about your child. De-identified information about your child that was already collected up to the point that you withdrew your child 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 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](mailto: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 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 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 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) holds insurance policies which apply to this study. If in the unlikely event your child experiences serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that UMCU is at fault. This does not affect your legal rights to seek compensation. If your child is harmed due to someone’s negligence, then you may have grounds for a legal action.

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

All information about your child, their health and their participation will be kept private. The only people who will have access to this information are your child’s doctors and nurses looking after them 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 child’s 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 anonymous 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 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 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 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.**

Text

Description automatically generated with low confidence

Information for younger children

(read with parent/guardian/caregiver)

**A close-up of a toy

Description automatically generated with medium confidence**

You are in the Hospital because you are not feeling very well.

The doctors and nurses at the hospital will do all they can to help you feel better.

We are testing some medicines that might help you feel better faster. Your parents will decide if you can try these medicines as part of our study.

**What will happen?**

**Icon

Description automatically generated**

**A picture containing text, vector graphics

Description automatically generated**In our study your doctors and nurses will check you and make sure it is safe for you to have these medicines. We may take some swabs from your nose.

After you leave hospital, we will call you in a while and check how you are feeling.

Once we have tested many grown-ups and children we will know if these medicines work.

If you have any questions, you can ask your parents or your doctors and nurses.

**CONSENT FORM FOR PARENTS/GUARDIANS/CAREGIVER**

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

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

I, *(forename and surname)*……………………………………………………………………………………………… freely agree for my child

………………………………………………………………………………………………………………………………………..to take part in the study.

|  |  |
| --- | --- |
|  | 1. I confirm that I have read and understood the relevant patient information sheet for the above study and have been able to ask questions which have been answered fully. |
|  | 2. I agree to for my child take part in the following domains: - **influenza 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 child’s participation is voluntary, and we are free to withdraw consent for this at any time, without giving any reason and without my child’s medical care or legal rights being affected. |
|  | 4. I understand my child’s identity will never be disclosed to any third parties and any information collected will remain confidential. |
|  | 5. I agree that my child’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. |
|  | 6. I agree that I will not seek to restrict the use to which the results of the study may be put. |
|  | 7. I understand I will be contacted by ICNARC or my local hospital in six months to ask about my child’s quality of life and wellbeing. |
|  | 8. I understand that minimal randomisation data collected about my child will be transferred outside of the EEA. |

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Name of parent/guardian/ Signature Date

caregiver

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of staff member Signature Date

*(Listed on delegation log)*

*If the parent/guardian/caregiver is* ***not able*** *to write/sign, 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)*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of witness Signature Date

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

**ASSENT FORM FOR CHILDREN <10yrs OLD**

**(to be completed by the child and their parent/guardian/caregiver)**

**REMAP-CAP**

Child or young person (or if unable, parent on their behalf) to circle all they agree with

|  |  |
| --- | --- |
| Do you understand what this study is about? | Yes/No |
| Have you asked all the questions you want? | Yes/No |
| Do you understand the answers that were given to your questions? | Yes/No |
| Are you happy to take part? | Yes/No |

If any answers are ‘no’ or you don’t want to take part, do not sign your name

If you do want to take part, you can write your name below

Your name **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Date **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

The doctor or nurse who explained this study to you needs to sign too:

Print name **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Sign **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Date **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Thank you for your help.

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