**REMAP-CAP**

**Information Sheet and Consent form**

**for parents/guardians/caregivers of children 10 to 15 years old.**

**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) or influenza (flu) to participate in our research study. This study is trying to find the best treatments for these 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 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 or flu.

**What treatments are being investigated?**

We are testing treatments in patients who have been admitted to hospital.

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

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

*(please delete treatment if site not participating)*

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

Children and young people who have been admitted to hospital who have or are suspected to have pneumonia or flu. 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 your child has been randomised, depending on the treatment, depending on the treatment a nose swab sample may 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. Young women will also have a urine test for pregnancy as some treatments may not be suitable. The doctor or researcher will explain the study to you and your child, but neither they nor you can decide on the treatment allocation. You and your child can choose to withdraw from the study at any time, without giving any reasons.

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 (or your child’s) 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 they cannot be directly identified by this.

**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 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 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.

**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 child’s treatment will be stopped immediately.

**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 or telephone: -0207 594 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.**

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**Information for children 10 to 15 years old**



We wish to tell you about our research study. You are in hospital because your doctor thinks you are not very well because of an infection. Infections can be caused by different things, one of these are viruses which can cause problems like coronavirus and flu.

We want to test some new treatments that might make you and others like you feel better. Treatments change all the time and it is up to us to find out if there are better treatments that we can use to make people feel better quicker.

We are testing a few different treatments. We have listed these in more detail in a form for your parents and you can also have a copy if you like. The treatments include medicines for colds/flu, steroids which help reduce swelling in the body and medicines that help your body fight bugs. All the treatments we are testing have been used before for other things in people your age, and we want to know if they also work for flu, and pneumonia.

We are inviting young people like you who are admitted to hospital with the flu. Your doctor will tell you if you are suitable for our study and will let you and your parents know which treatments are available.

If you and your parents decide to take part in our study then this is what will happen next:-



* Your doctor or nurse will explain the study to you
* We will enter your initials, your age, if you are a boy or girl and information about your illness on our computers
* Our computer will then pick some treatments for you, this is done automatically, we don’t know which ones will be chosen.
* Depending on which treatment you get you may be asked to take a tablet or have an injection
* We may take some nose samples from you, until you leave hospital
* Young women will have a urine test for pregnancy to make sure nobody having a baby takes the test medicine.
* We will contact your parent 6 months later to see how you are
* We will collect data about you from other databases

You may not feel better, but you are helping us learn if our treatments work or not.

There can be side effects to some of these treatments, these are like side effects you might have after taking other medication. Your doctor will keep a close eye on you and if they are worried about any side effects they will stop the treatment.

You and your parents can decide to stop the treatment and being in the study whenever you like. If you do this your doctors will continue to provide other treatments if you are still unwell.

If you and your parents are happy to take part we will ask your parents to sign a consent form and for you to also sign an assent form to confirm you are happy.

If you have any questions please ask your parents or your doctor and nurses. We also have a study website which has more information about our study:- [www.icnarc.org/Our-Research/Studies/Remap-Cap/](http://www.icnarc.org/Our-Research/Studies/Remap-Cap/).

We will keep all the information we collect about you private. Only your doctors and nurses looking after you, and people who are running this study will see any of your information. We have more information about how we keep the information private on our website:- <https://www.icnarc.org/Our-Research/Studies/Remap-Cap/About>

We will put the findings of the study on our global website:- <https://www.remapcap.org/> we will also present our study at meetings and in papers. None of your personal information will be presented.

We have received money for this study from the European Union (Rapid European COVID-19 Emergency Research response (RECOVER) and from the UK National Institute for Health and Care Research (NIHR). The UK lead of the study is called Professor Anthony Gordon and he works at Imperial College London.

Before we can start a research study we need permission from a separate committee. Our permission was given by the London-Surrey Borders HRA Ethics Committee. They checked our study plan and made sure we had the right paperwork and the right people to run the study.

**CONSENT FORM FOR PARENTS/GUARDIANS/CAREGIVERS**

|  |  |  |  |
| --- | --- | --- | --- |
| **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.

|  |  |
| --- | --- |
|  | 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. |
|  | 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)* |
|  | 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. |
|  | I understand my child’s identity will never be disclosed to any third parties and any information collected will remain confidential. |
|  | 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. |
|  | I agree that I will not seek to restrict the use to which the results of the study may be put. |
|  | 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.  |
|  | 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 10 -15 YEARS OLD**

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

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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*