ARTIC PC

Antibiotics for chest Infections in children consulting with their GP

Parent Information Sheet **(Trial)**

(Version 5.0 25 August 2017)

What is the purpose of this study? You are being invited to consider allowing your child to take part in a research study to improve the care in general practice of children with chest infections. Before you decide whether you want your child to take part, please take time to read the following information carefully. The study aims to find which children with chest infections benefit from being prescribed antibiotics. Most children who see the doctor with a chest infection currently get antibiotics and the evidence from studies so far suggests that most children do not benefit from having antibiotics. The trouble with prescribing for the majority of such children is that we are using antibiotics too much which is causing the bacteria to become resistant, which is likely to lead in the future to serious infections for our children becoming untreatable from 'superbugs'. It is a real priority to show which particular children that GPs prescribe for currently benefit and which do not, so that antibiotics can be targeted better and the effectiveness of antibiotics can be conserved for future generations. This is the first time in the world anybody has done this particular research. The results will help develop national and, possibly international guidelines for doctors to use in the future.

Why has my child been chosen? Your doctor/nurse thinks your child is suffering from a mild or moderately bad chest infection based on the signs and symptoms (phlegm, fever, shortness of breath, or rattly noises heard in the chest when the doctor listens with the stethoscope) and thinks it is safe for your child to help in this study.

Does my child have to take part, and does this study affect my rights? Taking part in the study is voluntary. It is up to you and your child to decide. If you decide your child can take part, you are free to withdraw your child from the study at any time without giving any reason and without affecting your child's current or future treatment in any way. Taking part in this study does not alter your rights to compensation or right to complain under normal NHS procedures.

What will happen to my child if I take part, and what do I have to do? If you and your child decide to take part in the study, you will need to fill in and sign a consent form. If your child wants to, they may also fill in a form to say they are willing to take part. Your doctor or nurse will then:

- Ask you some questions about your child's chest infection.
- Give you some study medication for your child – which may be an antibiotic or a dummy antibiotic.
- Give you a study diary to fill in until your child is feeling better.

You may choose to allow the nurse to carry out all or some of the following tests:

- Take a throat swab from your child (to see what bugs they have that might be making them unwell). This will help us to see if the germs grown affect how long your child's illness lasts. If you would prefer your child not to give this, please just tell your doctor or nurse. The swab will only be used for the study and the results will not be routinely available to your GP.
- These samples, if you are willing, will be kept for future research into infectious diseases. This will allow us and/or other researchers to do further work on them in the future. Research for which

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they might be used could, for example, involve looking at other types of bugs or the importance of genes to work out how the immune system responds to infection. No information that could be used to identify your child will be given to researchers using the samples. Neither the samples nor anything in them or any information related to them will be sold or used to make money. You will be able to say on the consent form whether you would be happy for your samples to be kept and used in this way or not, and you do not need to agree to any of this in order to take part in this study.

- Take a finger prick blood sample from your child (to look at the levels of what we call inflammatory blood markers, these are changes that happen to all of us when we are unwell and used a lot in many countries to help decide treatment) .
- If you and your child are willing, we will also arrange for you to attend for a chest x-ray on your child in the next couple of days (Sometimes GPs miss pneumonia and this will help us to see how we can detect pneumonia in future better).

Your child may still take part in the rest of our study even if you decide not to let us take any of these tests.

This visit should take about 5 minutes.

- At the end of the 28 days you will be invited back to see your nurse or GP who will confirm the information you have given and we may ask you your child to perform a breath test which will be done by blowing into a special tube to measure how the lungs are functioning this maybe done 3 times to get an average reading (but only if they are over 6 years old). We will do this both before and after giving your child a medicine to open up the airways.

  This visit should take about 15 minutes.

Your child's study medication

- Your child's study medication will either be the antibiotic or a 'placebo' and will be given to you in a powder form which you will need to mix with water – you will be provided with a measure for making up the medicine. A placebo is an inactive preparation which is otherwise identical to the medication being studied. In this study, the placebo liquid will look and taste similar to the antibiotic liquid, but will not contain the antibiotic itself.
- We will ask you to give your child his or her study medication three times a day for seven days. Please ask your doctor or nurse to advise you if your child does not usually swallow medication.
- The type of study medication your child is given will be decided by chance, like a coin toss, and not by your doctor or nurse. Neither you nor your doctor or nurse will know whether your child has been given the antibiotic or the placebo liquid.
- The research team will also not know which type of study medication your child has been given until after the end of the study. They will only be told this sooner if any issues arise before the end of the study, which could affect the safety of children taking part.
- This is a normal part of research studies like ours. By giving some children the placebo liquid and others the antibiotic, we will be able to find out whether the antibiotics themselves really work.

What side-effects might my child get from the study medication?

- Most children will not have any side-effects from the antibiotic. However, up to 1 in 10 might get minor side effects such as a slight stomach upset (feeling sick, vomiting or diarrhoea). Other less common side-effects include skin rashes, dizziness and headaches.
- Unexpected serious allergic reactions to antibiotics can very rarely occur with symptoms such as lip swelling, throat tightness and difficulty breathing. If this happens, please seek medical advice or go to the hospital immediately

What if my child gets the placebo?

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- If your child gets the placebo, this does not mean that he or she is likely to get worse. The study in children so far suggests this is very unlikely.
- If your doctor or nurse had felt that your child needed antibiotics straightaway, he or she would not have invited you to take part in the medicines part of the ARTIC study.

Observational study

Sometimes either you or your GP or nurse may not want your child to do the medicines bit of the study, but may still ask you if you are willing to consider doing other parts of the study – which we call an 'observational study'. This is where we simply collect information about what happens to your child.

This would involve you talking to the nurse to answer some questions and then completing the daily diary.

Your study diary

This is for everybody in the study. We will ask you to fill in a diary about your child's illness and any complications which arise from this. In your diary, we will ask you to record:

- your child's symptoms (e.g. cough, shortness of breath, disturbed sleep) every day.
- when you give your child study medication and any other medication every day.
- any side-effects your child has from the study medication.
- any time you take off from work, and any time that your child takes off from school or nursery.
- your child's overall wellbeing after 1 week (day 7), 2 weeks (day 14), 3 weeks (day 21) and 4 weeks (day 28). We can send you reminders by text or e-mail.
- Whatever type of medication your child gets, someone from the research team will give you a call 2 days after your child enters the study to ask you how your child is and to see if you have any problems completing the diary. However, please seek advice from your doctor or nurse or take your child to hospital sooner if you think he or she is becoming much more unwell.

Your child may also fill in some questionnaires about him or herself – we will let you and your child decide this together.

Interviews

We may ask you, and your child if they are old enough, to be interviewed about taking part in the study. This will be up to you and as with all the other work everything is fully confidential and you would not be able to be recognise from what you tell us.

We will review your child's medical notes

We will collect some information from your child's medical notes about your child's health, medications, vaccinations and visits or telephone calls with a doctor, nurse or other healthcare professional.

Will any other information be collected?

With your permission GP notes will be accessed to find out about previous infections and treatments, and any other treatment or care your child might have needed for this infection. All these details will be kept fully confidential and used for research only.

What are the advantages and disadvantages of the study?

The main advantage is that you will help doctors and nurses better manage children with chest infections in the future, and your child will also have the opportunity to have an x-ray which would not normally be offered routinely in such cases. We will be seeing if this helps make the decision to prescribe antibiotics.

The disadvantages in taking part are the time involved to complete the diary and also the time to take your child to a local hospital for the x-ray including a very small dose of x rays and the final brief visit. X-rays

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produce potentially cancer inducing radiation and that the risks are 1 in 800,000 for females under 1 year and about 1 in 1 million for others, this is considered a very low risk and considered negligible by the Department of Health. Should your child be selected to receive the amoxicillin then there is also a small risk that they may suffer from side effects such as nausea, diarrhoea and occasionally a short term skin rash. If you agreed to the swabs and finger prick blood test these may cause some brief discomfort for your child.

What will happen to the results? The research will be published in medical journals. We will provide you with a summary of the results, but results will not be available for 3-5 years.

Will my taking part be kept confidential?

All the information will be kept fully confidential. Even your GP will not see your answers to the diary. Your child's name will not appear on any papers or reports. To keep the information confidential all diaries will be identified by a number only, and stored on password protected computers in locked buildings which are alarmed when staff are not there. The computer based systems have secure encryption to ensure confidentiality for any data collected or sent over the internet. Regulations require that diaries are kept in secure locked cabinets for 15 years, after which they can be destroyed.

Please state if you are happy for the information collected about your child to be used to support other research in the future. It will be shared anonymously with other researchers if you consent to this.

What if something goes wrong?

It is unlikely for anything to go wrong. However, the GP will want to see you again if your child's illness worsens. When necessary your doctor will take appropriate further actions. Also when new relevant information becomes available you and your doctor will be informed. Further patient insurance has been obtained for this study, as is the norm for patient studies, which covers any damage as a result of physical injury, caused by this research project. Each GP has their own Insurance and the University of Southampton insurance covers harm arising from the design and management of the research. If you have complaints about the study you can contact the researchers (see below) or use the normal arrangements in the health service.

Who is organising, reviewing and funding the research?

The study is funded and reviewed by the NHS Health Technology Programme, coordinated in four sites in England. The University of Southampton is coordinating the study locally. It has been approved by the Research Ethics Committee ,South-West Bristol Central reference number 15/SW/0300:

Thank you for taking the time to read this information sheet and considering participating.

What next?

If you are happy for your child to take part please sign the parental consent form now You may leave the top two copies of the consent with your GP in the freepost envelope and they will send the researchers their copy OR you may take the consent form home, sign it and post the two top copies in the freepost envelope one of which will go to the researchers and the other your GP. Take the bottom copy as your record of consent.

If you have any queries before you sign the consent form, or at any stage in the study please contact the study managers Gilly O'Reilly gor@soton.ac.uk or phone 02380591785. (N.B. this number is only for queries regarding the study; if you have an urgent medical problem please contact your doctor in the normal way).

In case of query or complaints you could also contact the Research Integrity and Governance team at the University of Southampton 023 8059 5058 Rgoinfo@soton.ac.uk .

You can also contact the Patient Advice and Liaison service line which provides general information about research. Your Local PALS contact https://www.nhs.uk/service-search/Patient-advice-and-liaison-services-(PALS)/LocationSearch/363 or phone NHS 111 for details of your nearest PALS.

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Data Protection Privacy Notice

Research at the University of Southampton is carried out to the highest standards. The University is publicly funded so it has to make sure that personal data (e.g. name, address, date of birth) is only used when it's the best thing to do for the public. This means that when you agree to take part in a research study, we will use information about you in the ways needed, as outlined, to carry-out and complete the research project.

The University's data protection policy about the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

The data we will be collecting for this study includes:

- Your name and contact details. This is to make sure that we can get in touch with you if we need to and to send you emails about the study.
- General information about you like your age, job status, height, weight and the type of cancer you had. This is for us to learn a bit more about the people taking part in the study and to make sure you see the right website pages.
- Questionnaire answers to see how you are feeling. This is to make sure that the study is right for you and to see if anything changes over time.
- Your answers to questions about treatment or support you've had. This is to see the different amounts and types of support different people have.
- Medical notes from your GP. These are collected at the end of the study, with your name and personal details removed. We use the notes to see if you have had any medical problems while you have been taking part in the study which might influence the findings of the study.

Please ask the research team if you have any questions or are not clear what data is being collected about you.

Our privacy notice for research participants has more information on how the University of Southampton collects and uses personal data when you take part in one of our studies and can be found at
http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will only beused for the research and will be handled in line with University policies and data protection law. If any personal data is used it will not be given to anyone else without your consent unless the University of Southampton is required to disclose it by law.

Data protection law means we have to have a valid legal reason ('lawful basis') to collect and use your Personal data. The lawful basis for using personal data in this research study is to explore how the Renewed programme might be useful for other members of the public. Personal data collected for research will not be used for any other reason.

For data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are in charge of looking after your information and using it properly. The University of Southampton will keep information which might identify you (for example, your name, age) for a maximum of 3 years after the study has finished when any link between you and your information will be removed.

To protect your rights, we will use as little personal data as we can for our study. Your data rights – like accessing, changing, or transferring your information - might be limited, but only for the study to be reliable and truthful. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or want to use any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

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