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PARTICIPANT INFORMATION SHEET

IRAS ID: 1008782

Empirical oral AntibioticS for possible urinary tract infection (UTI) in well appearing Young febrile infants

The **EASY** Study

We would like to invite your child to take part in our research study.

- Before you decide we would like you to understand why the research is being done and what it would involve for you and your child.
- A member of the study team will go through this information sheet with you. Please ask questions about anything that might not be clear.
- Please take time to read the information carefully and discuss it with family and friends if you wish.

Thank you for your time to consider participation in the EASY study

Why is this study being done?

Children between 1 and 3 months of age with a fever (raised body temperature) commonly undergo blood and urine tests to check for infection. They are admitted to hospital for a minimum of 36 to 48 hours to wait for results of their laboratory tests for infection and given intravenous antibiotics "just in case" while waiting for these results. Laboratory tests for infection involve watching to see if bacteria grow in the blood and urine samples over a period of 36 to 48 hours. As well as these slow tests for infection, babies will usually also have some rapid tests done on a blood sample (that take a few hours) which are used to help assess how unwell a baby is.

The most common infection requiring treatment with antibiotics, in babies aged 1 to 3 months is a urinary tract infection (UTI). These infections usually respond quickly to antibiotic treatment but can be difficult to diagnose. When doctors are unsure if there is a UTI, they often give intravenous antibiotics until the results of the laboratory tests for infection are available, which is typically 36 to 48 hours later.

Research has shown that babies aged between 1 and 3 months who appear well and have reassuring results from the rapid blood tests can be treated with oral antibiotics. Likewise, several international guidelines have been published that recommend oral antibiotics as first-line treatment for infants with a suspected UTI.

The aim of the EASY study is to determine if babies with a suspected UTI can be treated with oral antibiotics whilst they wait for their laboratory results. This approach has the potential to reduce the need for painful procedures such as injections, reduce hospital admissions with its associated stress for parents/guardians and reduce healthcare costs. We aim to recruit just under 600 patients to the study over the next three years from hospitals across the UK.

Why has my child been invited to take part?

Your child has been invited to take part in this study because they have a possible UTI, appear to be well, and have reassuring initial blood tests. Your child is suitable for either intravenous or oral antibiotics.

Does my child have to take part?

No. It is up to you to decide whether or not your child takes part. If you agree to them taking part you will be given this information sheet to keep and you will be asked to sign a consent form. You may still decide to withdraw your consent for your child to take part at any time without giving a reason. If you decide that your child should not take part, this will not affect your legal rights or healthcare at any time, now or in the future.

Your child will NOT be able to participate if they;

- Have evidence of a more serious infection other than a UTI
- Were born prematurely (below 30 weeks gestational age)
- They have a history of prior ill health requiring hospital admission
- Have received a vaccination within 48 hours of attendance
- Have abnormal kidney function tests
- Are unable to take oral medications

If your child's medical history and routine blood tests show that they can be in the study, we will also check with your child's doctor that they are happy for your child to take part.

What is standard care?

If you decide not to enter your child on the EASY study, your child will receive the standard intravenous antibiotic treatment for a suspected UTI. It is your decision whether you would like your child to take part.

What will happen if I agree for my child to take part in the EASY study?

If all your questions about the study have been answered and you are happy for your child to take part, a member of the study research team will ask you to sign a consent form and include your child in the study.

Your child will receive antibiotics, which may be given either intravenously, or by mouth.

To get a reliable result as to whether oral antibiotics are as effective as intravenous antibiotics, we need to make a fair comparison. This is done by putting participants into two different antibiotic treatment groups using a technique called randomisation. The two antibiotic groups are:

1. **Intravenous antibiotics (standard care)**
2. **Oral antibiotics**

A computer program will randomly select which antibiotic group your child will be in and you will be told the result. Neither you nor your child's doctor can choose which group your child will be in. Your child has a 50% chance of being in the group receiving oral antibiotics and a 50% chance of being in the group receiving intravenous antibiotics. Whichever group your child is in, they will still be looked after by the same team of doctors and nurses that are already treating them.

All the antibiotics used in this study are routinely used in the UK and no experimental drugs will be used. **No additional blood tests** will be required for this study.

Antibiotic Treatment Groups

Intravenous Antibiotic Group

If your child is assigned to the **intravenous antibiotic group** (standard care) they will continue to receive intravenous antibiotics at least until the laboratory results are known (typically after 36 to 48 hours). Your child will receive the standard intravenous antibiotics your hospital normally uses to treat a suspected UTI.

Once the results of the laboratory tests are known, the doctor looking after your child will decide how long they need to stay on intravenous antibiotics and if/when they can switch to oral antibiotics. Your child's doctor will determine when your child should be discharged home.

Oral Antibiotic Group

If your child is assigned to the **oral antibiotic group** they will receive oral antibiotics at least until the laboratory results are known (typically after 36 to 48 hours). Your child will receive the standard oral antibiotics your hospital normally uses to treat a suspected UTI.

If your child has been assigned to the oral antibiotic group they will either receive oral antibiotics in hospital or at home. Your child may be allowed home from hospital earlier than those in the intravenous antibiotic group and prior to the laboratory results are known.

If your child is allowed to go home, the doctors will provide you with information on how to administer the oral antibiotic to your child, including how much (dose) and how often (frequency).

If your child is allowed to go home (prior to the laboratory results are known), follow up assessments will be undertaken by the study team by telephone within 24 hours of being assigned to the oral antibiotic treatment and again when the results of the laboratory tests are known (typically between 36 and 48 hours). You will also be provided with emergency contact details, if you are concerned or have any questions during those first 24 to 48 hours (see contact details below).

There is a small risk that your baby may not take the oral antibiotic or vomit after taking it. If this happens, they may have to be re-admitted to hospital. If there are signs the UTI is not being successfully treated your child's medical team will quickly organise any additional treatments that your child may require. They may have to be re-admitted for further antibiotic treatment in hospital.

Once the results of the laboratory tests are known, the doctor looking after your child will decide how long they need to stay on oral antibiotics for or they may change or stop the antibiotics depending on what they think is the best treatment for your child. The doctor will discuss this with you.

Follow Up Interviews and Questionnaires

On Day 1, you will be asked to complete a quality of life questionnaire. On Day 2 you will be asked to complete a short questionnaire on how you were informed about the EASY study. If your child has been discharged home, we will ask you to post these in the stamped addressed envelope provided.

At the end of the first week Day 7 (+/- 1 day), we will check on your child's progress. A follow up interview will be completed by telephone and should last approximately 15 minutes. A member of the study team will contact you to arrange a convenient time to complete the follow up interview. On Day 7 they will check whether your child:

- Completed the planned course of antibiotics
- Changed antibiotics or whether any further antibiotics were required
- Had any possible side effects/complications from the antibiotic treatment
- Were readmitted to hospital
- Symptoms over the course of the week

We will also ask you to complete two quality of life questionnaires, which we gave you when your child started the study and to post these in the stamped addressed envelope provided.

At the end of the fourth week Day 28 (+/- 3 days), we will check on your child's progress. A follow up interview and questionnaire will be completed by telephone and should last approximately 15 minutes. A member of the study team will contact you to arrange a convenient time to complete these. On Day 28 they will check whether your child:

- Completed the planned course of antibiotics
- Changed antibiotics or whether any further antibiotics were required
- Had any possible side effects/complications from the antibiotic treatment
- Were readmitted to hospital
- Symptoms over the course of the last few weeks

We will also ask you to complete a quality of life questionnaire, which we gave you when your child started the study and to post this in the stamped addressed envelope provided.

The study team will also review your child's medical notes to help answer these questions, particularly if your child has required further medical assessments since they were discharged home. The study team may also contact your child's GP practice to help answer these questions.

The study calendar below shows what will happen during the study.

Study Calendar

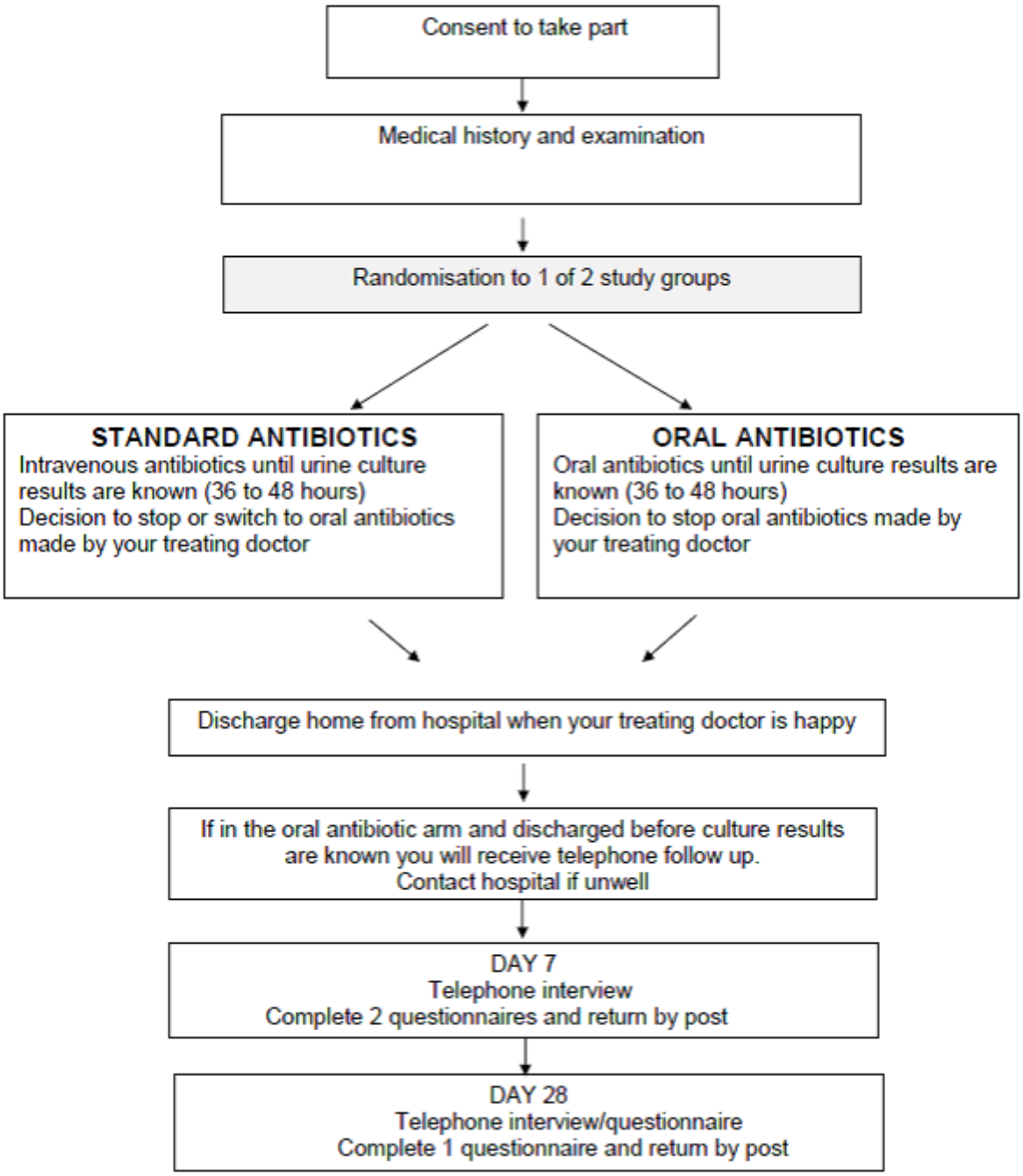
Day/week	What will happen
After admission to hospital	Meet the doctor and study team. Receive Participant Information Sheet. If agreeable, provide informed consent for: •Taking the antibiotic treatment for the study group your child is allocated to. Once you have consented: •Your child will have their medical history checked. •You will be told which antibiotic treatment group your child has been allocated to.
During your child's hospital stay	Your child will receive the antibiotic treatment they have been allocated. If the doctor doesn't think your child's antibiotic treatment is working they will make changes. The doctor will discharge your child home whenever they feel they are ready.
Day 1 (24 hours)	If your child is in hospital they will have a medical review as part of their standard care. This is known as a "ward round". If you child has been discharged home with oral antibiotics this review will be conducted by telephone.
Day 2 (36 to 48 hours)	If your child is in hospital they will have a medical review and review of their laboratory results as part of their standard care. If you child has been discharged home with oral antibiotics this review will be conducted by telephone.
Day 7	Telephone interview with study research nurse who will check on your child's progress and remind you to complete and return the two questionnaires.
Day 28	Telephone interview with study research nurse who will check on your child's progress and remind you to complete and return the questionnaire.

What happens when my child's involvement in this research study stops?

Your child will continue to be looked after by their normal doctors. If your child requires further antibiotics for another infection they will not be asked to take part in the study again and the antibiotics your child will be given will not be influenced by this study.

Study Flow Chart

Another way to find out what will happen to your child during the study is to read the study flow chart below. Start reading at the top and read down the list, following the lines and arrows.



What are the possible benefits of taking part?

The overall aim of the study is to provide information about how effective oral antibiotics are in infants who present to hospital with a possible UTI and no features of more serious infections. There is no guarantee your child will directly receive added benefits from the treatment they receive in this study, we are trying to find out the best treatment for future patients who have a possible UTI. If your child is in the group receiving the standard intravenous antibiotics they will receive the same antibiotic treatment most infants receive when they present to hospital with suspected UTI. We believe that oral antibiotics are a safe and effective alternative to intravenous antibiotics but this cannot be guaranteed. We also believe oral antibiotics may have several advantages for your child including:

- A better quality of life during treatment
- Fewer complications or difficulties with intravenous lines
- Earlier discharge home from hospital

What are the possible disadvantages and risks of taking part?

Potential risk of antibiotic treatment failure

There is a risk for children in the oral antibiotic group that their infection may not resolve as quickly compared with those who continue on intravenous antibiotics. This might require a change of antibiotics or a switch back to intravenous antibiotics. If your child has been discharged home, there is a small chance they may need to come back to hospital and possibly be readmitted if doctors feel their infection is not settling or they are becoming more unwell.

Potential side effects of antibiotic treatment

The various antibiotics used to treat your child's infection all have different side effects, which the doctor looking after your child will explain. In general oral antibiotics are more likely to cause nausea and vomiting than antibiotics given by injection. Both oral and intravenous antibiotics may cause diarrhoea or rash. The initial insertion of an intravenous line involves some discomfort but this is usually mild. Intravenous lines have a small risk of becoming infected themselves and very occasionally can cause irritation in the vein or fall out. If this happened the line would be removed and re-sited. It is important to remember these risks are no different whether you take part in the study or not as it is currently standard practice to give antibiotics intravenously for febrile infants with a suspected UTI. If your child has any side effects or complications that may be related to an antibiotic or an intravenous line, you must tell the doctors or nurses looking after them.

What will happen if I don't want my child to carry on with the study?

You can withdraw your child from the study at any time without giving a reason and your child's care will not be affected. Your child will continue to be looked after by the normal team of hospital

doctors and nurses and will receive the treatment they feel is best for your child's infection. If you decide to withdraw your child from the EASY study, you should contact the study team at your hospital. If you withdraw your child from the study, we would use the data collected up to the time your child was withdrawn from the study.

What if something goes wrong?

The NHS hospital remains responsible for your child's care during the study. If you have a concern about any aspect of the way you have been approached or your child has been treated during the course of the EASY study, please contact the local Principal Investigator (contact details below), who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the normal NHS complaints service for your hospital (contact details below). In the event of your child suffering harm as a result of taking part in this study, due to someone's negligence, then you may have grounds for a legal action for compensation but you may have to pay your legal costs.

Will information from the study be kept confidential?

Any information which is collected about your child during the course of the study will be kept strictly confidential and will only be seen by staff involved in the study from the NHS Trust, the Trial Co-ordinating Centre (Northern Ireland Clinical Trials Unit), Belfast Health and Social Care Trust and people from regulatory authorities who ensure that studies such as this are carried out correctly. All of them will have a duty of confidentiality to your child as a research participant. Because we will need to contact you after your child leaves hospital, the NHS Trust will need to keep a record of your name, address, and other contact details such as telephone number and email address. You have the right to see your child's personal health information related to the research study, but you will not be able to review some parts of the information until after the study has finished. When any information from the study is published, it will not contain personal information and it will not be possible to identify any individual participant.

The data from this study will be kept for at least twenty-five years after its conclusion and will be retained by the Trial Co-ordinating Centre, Belfast Health and Social Care Trust. The data may be shared and used in other research studies but if it is used in this way all personal identifiers will be removed and it will not be possible to identify any individual.

What will happen to the results of the research study?

Recruitment will commence in 2024 and the study is expected to take 3-4 years to complete. It is envisaged that publication of the results will follow shortly after this, through medical journals, websites, press releases, and via appropriate support groups. The results will also be presented to other doctors and nurses at meetings and conferences. Names of participants will not appear in any reports or publications arising from the study. You will be able to request a summary of the main

results either from the study team at your hospital or through the Trial Co-ordinating Centre whose contact details can be found at the end of this information sheet.

Who is organising and funding the study?

The EASY study is being organised by a group of clinicians and led by Dr Tom Waterfield a Senior Academic at Queen's University Belfast and a Consultant in Paediatric Emergency Medicine at the Royal Hospitals, Belfast, Northern Ireland. The EASY study is funded by the National Institute for Health and Care Research, Health Technology Assessment Programme. The sponsor of the study is the Belfast Health and Social Care Trust. The study sponsor makes sure the research is conducted to a high standard to safeguard patient safety and data. There are no payments or reimbursement of expenses available to study participants.

Who has reviewed the study?

This research has been reviewed and given a favourable opinion by an independent group of people, called a Research Ethics Committee (REC), to protect your child's safety, rights, well-being, and dignity. The Ethics Committee is completely independent from the study team. The study has also been reviewed by the regulatory body, the Medicines and Healthcare Products Regulatory Agency (MHRA). Your local NHS trust has given approval for the study to take place at your hospital.

Will my child's GP be informed of their participation in the study?

With your permission we will inform your child's GP of their participation in the study and they may be asked to provide information about your child e.g. hospital admission and antibiotic prescription details.

What happens if I have any questions, concerns or complaints about the study?

If you have any questions about your child's participation in this study or concerns about the way it has been carried out, you should contact the local Principal Investigator or a member of the research team at your hospital (contact details below).

How long can I think about my child joining the study?

Once your child has been confirmed as eligible for the study you will have up to six hours to make your decision.

Thank you for taking the time to read this Information Sheet

Contact Details

If your child is taking part in the study and you are concerned that they have become more unwell, it is important you contact your hospital immediately on.

HOSPITAL NAME: **«name»**

IN HOURS (8am – 8pm): **«telephone»**

OUT OF HOURS (8pm – 8am): **«telephone»**

For any questions about the study you may contact the research team during work hours using the contact details below:

Principal Investigator: *Update with local details*

Name: «name»
Address: «address»
Telephone: «telephone»

Complaints/concerns: *Update with details for local complaints department and/or Patient Advice and Liaison Service.*

Name: «name»
Address: «address»
Telephone: «telephone»

Chief Investigator:

Name: Dr Tom Waterfield
Address: «address»
Telephone: «telephone»

EASY Trial Co-ordinating Centre:

Address: «address»
Telephone: «telephone»
Email: «telephone»

Transparency Statement

Belfast Health and Social Care Trust is the sponsor for this study. The study sponsor is the organisation responsible to ensure the study is carried out to a high standard to safeguard patient rights and safety, and the quality of the research data.

How will we use information about your child?

We will need to use information from you, your child's medical records and your child's GP.
This information will include your child's initials, NHS/Hospital Number, your name and contact details (including email). People will use this information to do the research or to check your child's records to make sure that the research is being done properly. People who do not need to know who your child is, will not be able to see your child's name or your contact details. Your child's data will have a code number instead.

We will keep all information about your child safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

What are your choices about how your child's information is used?

- You can stop your child being part of the study at any time, without giving a reason, but we will keep information about your child that we already have.
- If you decide to stop your child from taking part in the study, we would like to continue collecting information about their health from their hospital, and their GP. If you do not want this to happen, tell us and we will stop.
- We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about them. We can provide a list of the type of information we are collecting, upon request.
- If you agree for your child to take part in this study, you will have the option for your child to take part in future research using the data saved from this study.

Where can you find out more about how your child's information is used?

You can find out more about how we use your child's information

- at www.hra.nhs.uk/information-about-patients/
- www.belfasttrust.hscni.net/about/access-to-information/data-protection/
- by asking one of the research team
- by sending an email to the EASY study team: EASYSTUDY@nictu.hscni.net, or
- by ringing us on «telephone»