Information leaflet for the EXTEND study:

The EXTEND study is looking at the antibiotic treatment of patients treated for serious abdominal infections (gut infections). It will see if a fixed 28-day course of antibiotics is better or not than an antibiotic duration decided by a doctor (normally 7 to 18 days).

<<insert Hospital name>> and York Trials Unit would like to invite you to take part in a research study. You have been chosen because your nurses or doctors have diagnosed you with an infection within your gut that needs to be treated with antibiotics.

Before you decide whether to take part, we would like you to understand why we are doing this study and what taking part would mean for you. Please read the following information carefully. If you wish, discuss it with your relatives, friends, clinical care team or research nurse. We are very happy to provide more information if anything is unclear. Our contact details are at the end of the leaflet.

This page has key information about participation in the EXTEND Study. Page 2 has a contents list. It may take up to 30 minutes to read the full leaflet. However, it is designed to be read one section at a time.

What is the EXTEND study?

- People with intra-abdominal infections (gut infections) are treated with antibiotics. These are routinely prescribed to patients for between 7 and 18 days. However, in half of patients the infection returns or a new infection develops. This is referred to as treatment failure.
- This study aims to find out if taking antibiotics for 28 days prevents treatment failure.
- Patients who take part will be assigned to either the standard duration of antibiotics as decided by their doctor (usually 7 to 18 days) or a fixed 28-day duration.
- Everyone participating in the study will be cared for in line with NHS requirements. No experimental drugs or placebos will be given.
- We will ask that a questionnaire is completed at the start of the study, then after 1, 3 and 6 months. This is to see how your quality of life has changed since the start. Your doctor or nurse will pass information on to the study team regarding treatment failure during this time.
- We hope to have the participation of 1166 patients with intra-abdominal infections (gut infections) from hospitals across the UK in order to conduct the study successfully.

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Why is this research being done?

Infections within the abdomen of patients can be difficult to treat. Antibiotics are prescribed to help cure the infection. Antibiotics are usually taken until a patient feels better, which is normally within 7-18 days of starting antibiotic treatment. The choice of duration varies because there is limited evidence on what duration is best. Unfortunately, after treatment with antibiotics these infections can return.

Research from other studies has suggested that longer courses of antibiotics may offer benefits for patients with serious abdominal infections. Longer courses of antibiotics could be better at curing and preventing infections. They may also be better at keeping patients out of hospital. However, these studies are too small to say for sure. Additionally, longer courses of antibiotics may be associated with more side effects (you can read more about these in the section "**What are the possible benefits/disadvantages of taking part?**"). Therefore, this study aims to see if a fixed 28 day duration of antibiotics is overall better for treating patients with serious abdominal infections than shorter courses of antibiotics (normally between 7 to 18 days) as decided by a doctor.

In summary, this research is important to help us learn more about the best duration of antibiotics for patient with an abdominal infection. With the information that we learn, we will be better able to help patients with abdominal infections get better.

This is not-for-profit research carried out for the benefit of patients and not for any commercial reasons.

What will it involve?

How will it affect my treatment?

If you join the study, the length of antibiotics you will be given will be decided at random. You will either be given antibiotics until you are feeling better (usually between 7 to 18 days), or you will be given 28 days of antibiotics. The antibiotic and the way it is given (e.g. as a tablet or through a drip) will be decided by your doctor. This is to ensure you get the most suitable antibiotic for you. It will be a routinely used antibiotic for the type of infection that you have. No experimental drugs or placebos will be used. The only difference to treatment if you take part is the potential for antibiotic treatment to be fixed to 28 days.

If you have side effects, you do not have to keep taking the same antibiotic. Your doctor will try to find one that is more suitable, as is standard practice. The antibiotics do not have to be given in hospital (they can be taken as tablets or by drip in your own home), so you should not have to stay in hospital any longer if you are feeling better.

If you choose not to take part, you will still have antibiotics until you are feeling better, usually up to 18 days.

What would I have to do?

We would like you to fill out a questionnaire at the start of the study and then 1, 3 and 6 months later. It will take about 10-15 minutes to complete each time. A carer, friend or family member can help you to complete this if needed.

We will email or text you a link, or give you a phone call to complete your questionnaire based on your preference. The research nurse can provide a paper questionnaire if you cannot access the electronic questionnaire while in hospital. We can arrange a phone call to discuss options for follow-up questionnaires after you have been discharged if you are unable to do these electronically. If it would help to see what the questionnaire contains before agreeing to take part, please ask the research nurse.

The questionnaire will measure your quality of life by asking whether you have any problems with mobility, self-care, your usual activities, pain/discomfort and anxiety/depression. It will also ask about whether you have taken any more antibiotics or needed any more healthcare. We will ask you to complete additional questions after 1 month, to find out how many days you took antibiotics for.

Is there anything else involved?

As a thank you for taking part, you will be offered a £20 Love2Shop voucher at 1, 3 and 6 months after you join the study. This will be offered at the same time we send the questionnaire. Vouchers can be exchanged for e-Gift cards for more than 40 shops including supermarkets, high street shops and online shops.

Do I have to take part?

It is entirely up to you to decide whether you want to take part in the EXTEND study or not. If you do not want to take part, you will receive antibiotics until you feel better, as is normal NHS practice.

If you decide you would like to take part, you will be asked to sign a consent form. If you change your mind later, you are free to withdraw from the study at any time, and this will not affect your normal medical care. If you do withdraw however, any data collected before that point will still be used in the study. You can choose to allow the study to continue collecting data from your hospital records only or to fully withdraw and stop all future data collection.

The infection that you have can be serious and a small number of patients may become incapacitated as part of their treatment, for example, if you have an operation or need to be sedated. These decisions are made by your doctor and only when necessary. In the unlikely event that this happens to you while you are enrolled in the study, you will continue to be enrolled in the study if you state this on the consent form.

If you provide consent, we will continue to collect data about you while you are incapacitated. Where this lasts for more than 72 hours, a friend, relative, or medical professional will be asked to consider whether continuing to take part in the study remains in your best interest and sign a declaration form if they think you should stay in the study. Just in case we need to ask someone to do this, you can tell us who you want to take on this responsibility when you sign the consent form. If this person agrees, the treatment you get as part of this research project will continue to be given and your medical information relating to treatment failure will continue to be collected. We will ask you if you still want to continue taking part in the research once you regain capacity. It's up to you to decide whether to continue to take part in the study or not at that time.

What are the possible benefits/disadvantages of taking part?

Possible benefits

One of the most important things we want to look for in this research is to see if the number of days antibiotics used is related to the risk of infection coming back. If you have a shorter course of antibiotics, it may be more likely that your infection returns after stopping antibiotics. We will only be able to find this out with certainty if 1166 patients take part in the study. This information will benefit other patients (including yourself) who have this type of infection in the future.

Possible disadvantages

The potential disadvantages relate to side effects of the antibiotics. If you have a longer course of antibiotics you may have more side effects from the antibiotics. It may be more likely you will have a common side effect (affect approximately 1 in 10 patients) like diarrhoea. There may be more chance of uncommon side effects (affect approximately 1 in 1,000 to 1 in 100 patients) such as infections that are resistant to some antibiotics. These infections can occur in your bowel such as one called Clostridium difficile.

If at any time you think your infection might have returned, or you think you might have a side effect from antibiotics we would advise you to discuss with a health care professional looking after you.

What if there is a problem?

If you have any concerns while taking part in the study, you can contact the research team using the contact details on page 5.

If you have any medical complications while taking part in this research, there are no special compensation arrangements as no experimental treatments are given. The drugs you receive will have undergone rigorous safety testing and are approved for routine use in the NHS. However, if the complication was because of someone's clinical negligence then you may have grounds for legal action for compensation against the NHS (in respect of any complication which has resulted from a clinical procedure being undertaken). Regardless of this if you wish to complain about any aspect of the way you have been approached or treated during the course of the study, the normal NHS complaints mechanism is available to you.

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

You can withdraw from the study at any time, and this will not affect your normal medical care. If you do withdraw however, any data collected before that point will still be used in the study. . Additionally, if you withdraw from the study, we still have an obligation to report to the ethics committee any serious adverse reaction you have which is related to being in the study.

Will my taking part in this study be kept confidential?

We will keep your identity confidential at all times. We will ask for your permission to let your GP know that you are involved in the study. The hospital research nurse/doctor will access your medical notes to collect information on your medical background. They will see your name and medical information but will not disclose these to anyone else. By signing the consent form, you are authorising the research nurse/doctor to review your medical notes for the 6-month duration of the study. The consent form and your contact details will be passed on to the University of York Trials Unit. They are running the study and need these to send questionnaires and study updates to you. They will also receive medical information that is relevant to the study but it won't contain your name or address, only a study number.

We store electronic information on password protected NHS and University of York computers, separately to your personal information. Written information will be stored in a safe and secure location.

If you agree to take part in the study, the University of York, and <<insert hospital name>> will keep data collected for a minimum of 5 years. The university will then arrange confidential destruction. They will confidentially destroy identifiable information collected about you (such as name, address, date of birth and contact details) at the end of the study, unless you have agreed to be contacted about future research.

How will you use information about me?

We will need to use information that you provide and your medical records for this research project. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

To check that the study is being carried out correctly, your medical record may be looked at by authorised people. All will have a duty of confidentiality to you as a research participant. The information will be anonymised for data analysis and publication. Individuals from the Sponsor, the University of Leeds, may have access to the medical records for this purpose. This information will include your name, contact details and medical history. People will use this information to do the research or to check your records to make sure that the research is being done properly.

We will keep all information about you 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 you took part in the study.

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- from our leaflet available from www.hra.nhs.uk/patientdataandresearch
- from the University of Leeds privacy notice at https://ris.leeds.ac.uk/privacy-notice/
- from the University of York privacy notice at https://www.york.ac.uk/records-management/dp/your-info/generalprivacynotice/
- by emailing the University of Leeds data protection officer at dpo@leeds.ac.uk
- by asking one of the research team

What are my choices about how my information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop. You can contact us any time by emailing ytu-extend-trial@york.ac.uk or through the research nurse.

We need to manage your 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 you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Who is organising and funding the study?

The study is being funded by the National Institute for Health Research Health Technology Assessment Programme (Project Number: NIHR131784). The University of Leeds is the study sponsor. They are responsible for the study, supported by York Trials Unit.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. The aim of a Research Ethics Committee is to protect your interests. This study has been reviewed by the Leeds West Research Ethics service.

How have patients and the public helped to design the study?

Patients and members of the public have confirmed the importance of this research question, have reviewed this information leaflet and other study documentation, and have advised on the best questionnaires to use in the study.

What happens to the results of the study?

The findings of the study will be published in scientific journals. All data will be anonymised so that readers won't be able to identify you from the published information. We will ask you if you would like to receive a copy of the results of the study.

Additional information

Most antibiotics are safe in pregnancy, but please contact the research team or a health care professional if you become pregnant during the study.

We will not be collecting samples from you as part of this research project.

The information collected in this study may be used to support other research in the future. Any information shared will be done so anonymously.

Contact Details

We encourage you to ask any questions before joining this study. If you have any questions or require further information before or during the study, please contact:

[insert PI or lead research nurse name]
Telephone: [insert number]
Email: [insert email address]

If you would like independent advice about whether or not to take part, the Patient Advice and Liaison Service (PALS) can be contacted on [insert number] or at [insert email address.]

If you would like specific information about this study, you may contact the study team at ytu-extend-trial@york.ac.uk.

If wish to make a complaint, please contact the study team first at ytu-extend-trial@york.ac.uk to see if the issue can be resolved. If you wish to make this a formal complaint you can contact the sponsor representative Clare Skinner by email to governance-ethics@leeds.ac.uk.

Useful Links

https://bepartofresearch.nihr.ac.uk/

https://www.york.ac.uk/healthsciences/research/trials/research/trials/extend/

- Scan the QR code with your smartphone to access the EXTEND web page and a video describing the trial.