(To be printed on local headed paper)

Cellulitis Optimal Antibiotic Treatment

Participant information sheet

Short 5-day course compared to longer 7-day course of oral flucloxacillin antibiotic for cellulitis in the leg

Cellulitis **O**ptimal **A**ntibiotic **T**reatment **(COAT)** Study

- You have been given this information sheet because you might like to take part in the COAT study.
- We would like to invite you to take part because you have been diagnosed with cellulitis.
- Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it will involve.
- Please take your time to read this information carefully. You may also wish to discuss it with your healthcare professional or someone else before making up your mind.

Central COAT study team: 02381 550206 or email: coat@soton.ac.uk

(Please do not send any personal information to the above email address)

Do I have to take part? No. It is entirely up to you if you take part in the study or not. If you choose not to take part, the care you receive from your own doctor or nurse will not be affected in any way.

If I start the study, can I stop if I want to? Yes. If you choose to take part in the study, you are free to stop at any point without giving a reason, and without affecting the care that you receive.

What is the study about?

Cellulitis is a deep skin infection. Most people with cellulitis in the U.K. are treated with the antibiotic flucloxacillin for 7 days. However, research studies show that short courses of antibiotics (5 days or less) work as well as longer courses for many different types of infections, including serious infections like pneumonia. For cellulitis, there have been some studies that have shown that short courses work as well as longer course, and U.K. guidance recommends a 5–7-day course. However, there have not been any studies comparing short and longer courses of flucloxacillin prescribed outside of hospital settings (i.e. GP surgeries). Taking longer courses of antibiotics is likely to cause more side effects and kill off the 'good bacteria' that help keep us healthy.

The symptoms of cellulitis, like redness and swelling, are unlikely to have completely cleared by 5 days or 7 days. However, symptoms usually last longer than the actual infection. We want to see if the symptoms of cellulitis continue to get better in a similar way in people who take 5 or 7 days of antibiotics. Specifically, we want to make sure that people who take antibiotics for 5 days do not have more pain than those who take them for 7 days.

To watch a video explaining the study and for further information, please scan the code below which will take you to our study webpage:

https://www.southampton.ac.uk/ctu/coat-study.page

Important things to know about the COAT study

1) If you are happy to take part, you will need to complete a consent form via paper or an approved electronic consent system (depending on the process available at the healthcare facility you're being treated) to confirm that you understand and agree to take part in the study.
2) You will be given a normal NHS prescription for antibiotics to take for the first 5 days, so there will not be any delay in getting started on your antibiotics.
3) You will be put into one of two groups. Your group will be decided by chance: this process is called 'Randomisation'. You will have an equal chance of being put into each group.
4) Both groups will be sent a package of capsules to take on the 2 days after finishing the first 5 days of antibiotics. One group will receive 2 days of placebo (dummy capsule) and the other group will 2 days of oral flucloxacillin. The capsules will look the same so you will not know which group you are in. Please note that the study capsules contain gelatine.
5) You will be asked to answer some questions about yourself and your illness. A researcher will contact you by telephone to answer any questions and check that you are still happy to take part.
6) You will be asked brief questions about your cellulitis daily for the first 14 days and then once a week for a further 2 weeks. A friend/family member/carer can help you.
7) Your medical records will be looked at by researchers 12 months after you joined the study

Who is this study for?

People with cellulitis of the leg are being invited to take part. Your healthcare professional will discuss with you whether you are eligible to take part or not.

What will happen if I decide to take part in the study?

Depending on the location that you are treated at for your cellulitis, your journey through the study will follow one of the 2 pathways below:

Pathway 1

You will be asked to provide consent by signing a paper form with the healthcare professional at your initial consultation. Your GP will be informed of your participation in the study.

Pathway 2

We will ask you to provide consent using an electronic consent system. You can complete this during a phone call or video call with a member of the central COAT study team who will guide you through the electronic consent system. Your GP will be informed that you are taking part in the study.

Both pathways 1&2

You will then be asked to answer a few questions about yourself and your illness.

Your healthcare professional will prescribe an antibiotic (flucloxacillin) for you to take for five days. You will then be sent a pack containing capsules to take for a further two days. This pack will contain either antibiotic (flucloxacillin) or a placebo (dummy pill) and will look different from the capsules you were taking for the first 5 days. Please note that the study capsules contain gelatine. You will not know whether you have been given the antibiotic or placebo and the chance of treatment with either a 7-day course or a 5-day course is equal.

You will also be asked to fill out short online questionnaires about your cellulitis at the following times:

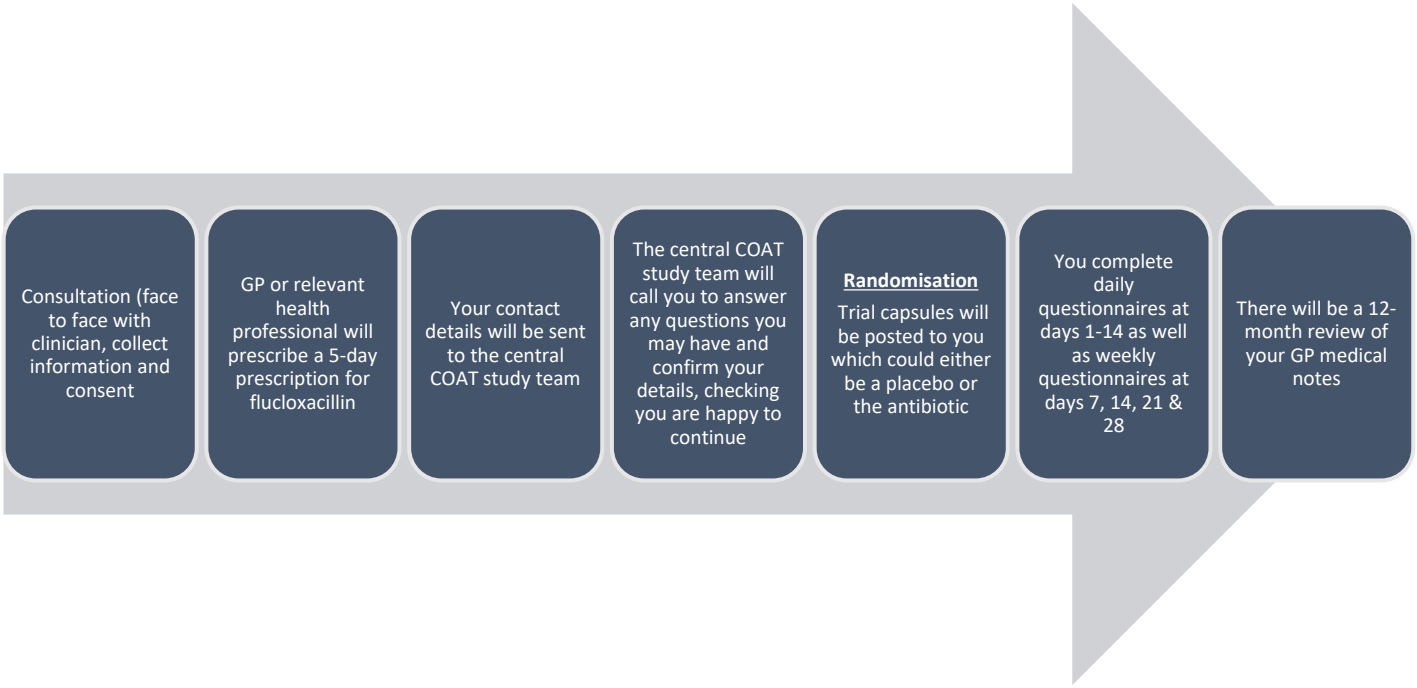
- Details about your illness and background (like gender and ethnic group) in an initial questionnaire (this may be completed at the time you join the study if you are in Pathway 2).
- Then very brief questions about your illness every day for up to 13 days.
- A few additional questions once a week for the first 4 weeks.

These questionnaires will be sent to you by an SMS (text message) or email link to an online form, or can be completed on paper. If completed on paper, we will provide you with pre-stamped envelopes to send the questionnaires back to us. In the unlikely event that your paper questionnaires do not arrive to your home address, we may contact you to collect the questionnaires over the telephone. We will also ask for your permission to review your medical records 12 months after you joined the study. This is to see if you developed any complications or recurrence of your cellulitis. We won't need to contact you about this.

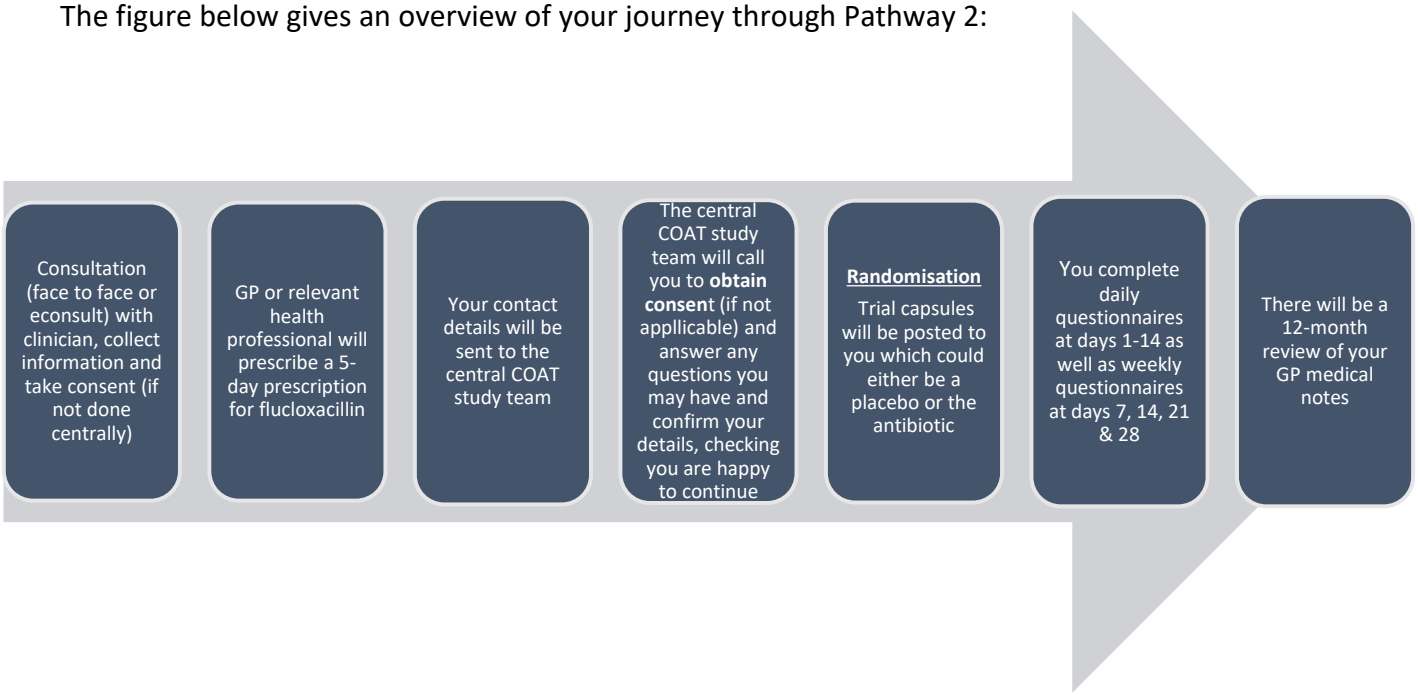
Your responses to the questionnaires will only be seen by the study researchers and will not be seen by your healthcare professional. Therefore, if you have any concerns about

your health you should report these to your GP surgery, NHS 111, or emergency services as you would if you were not in the study. They will be able to assess and treat you as necessary, including providing additional antibiotics if necessary.

The figure below give an overview of your journey through Pathway 1:



The figure below gives an overview of your journey through Pathway 2:



Possible benefits of taking part:

- You will be provided with information about cellulitis which you may find helpful.

- You may be given a shorter course of antibiotics, which may work just as well as a longer course and reduce the risk of side effects
- You will be helping to increase knowledge about how to treat cellulitis and this will benefit others with the same condition in the future.

Possible risks/disadvantages:

- Clinical studies are designed to reduce the risks and increase the benefits to the people who take part, regardless of which treatment they get. However, we cannot guarantee any specific treatment benefits or that there are no risks involved when taking part in a clinical study. The antibiotic being studied in this study is well known and has been routinely used by doctors to treat cellulitis since 1970.
- You will need to take the time to answer some questions about your illness.

Other questions you may have about the study

Who is funding the research?

This study is funded by the National Institute for Health Research. This is the main government funder for health studies in the NHS.

Will I get paid for taking part in the study?

The study is voluntary and you will not receive payment for taking part.

Where is the study taking place and who is running it?

The study is being run by a research team led by researchers at the University of Southampton. A group of patients who have had experience with cellulitis are also helping to make sure the study is as beneficial as possible. For instance, they have helped write this information sheet. The study is being sponsored by the University of Southampton and is being coordinated by the Southampton Clinical Trials Unit.

Do I have to take part?

No, taking part is entirely up to you. If you decide not to take part, you do not have to give a reason and your treatment will not be affected in any way. Deciding not to participate will not affect your legal rights. The treatment you receive will be decided by your healthcare professional in discussion with you. If you choose to be part of this study you can still choose to withdraw at any time. Any data already collected for the study will be kept, unless you explicitly tell us that you do not want data already collected to be used.

Can I take part in the study if I am pregnant?

Taking part in the study is not thought to represent any increased risk to pregnant women or their unborn child. Therefore, you can enter the COAT study if you are pregnant and can continue to take part if you become pregnant during the study.

How long do I have to decide?

You will need to decide before providing consent, which may be taken at the place where you are invited to take part, using a video call, or over the telephone. Ideally, you should try and come to a decision during your initial consultation with your healthcare professional, but, as you can be prescribed initial antibiotics at this time, you can have up to 48 hours from your consultation to decide if you want to take part. As long as you provide consent for your contact details to be provided to the central COAT study team, then someone from the University of Southampton will call you as soon as possible (usually between 48 and 72 hours) to answer any questions and check that you are happy to be part of the study. Once you have provided consent the study team will arrange for the extra 2 days of tablets to be sent to you. If you decide not to take part at any point, you should contact your GP surgery to discuss whether they wish to make any changes to your treatment and/or follow-up.

What happens if I change my mind?

You can withdraw from the study at any time. If you decide to withdraw from the study you will be given the choice to withdraw from treatment (and remain in the study for follow-up only) or withdraw from treatment and follow-up. If you withdraw from treatment only then the treatment of your cellulitis would be decided by the healthcare professionals looking after you and you would not take the study medication, but you would continue to complete questionnaires for the study. If you decide not to stay in the study for follow-up, your participation in the study will end, and you will not be asked to complete any more assessments. Your standard care will not be affected, and your decision will not prevent you from taking part in future research studies.

What happens if something goes wrong?

All research in the NHS is looked at by a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by North East - Tyne & Wear South Research Ethics Committee, REC ID: 23/NE/0021. Furthermore, this study has received Professional Indemnity and Clinical Trials Insurance from the University of Southampton, should something go wrong.

If you decide to take part in the COAT study and feel concerned about any part of the study at any point, you should contact the study team as soon as possible. The study team will do their best to help you and answer your questions.

If you wish to complain, or have concerns about any aspect of the way that you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism will be available to you. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay legal costs.

Availability of Research Results

The results of the study are likely to be published in medical journals. You will not be identified in any report or publication. We will also send a summary of the results of the study to you unless you tell us that you don't want to receive this. Personal details will be retained if you opt to receive a results summary.

How will we use information about you?

We will need to use information from you, from your medical records, and your GP for this research project.

This information will include your:

- Initials
- NHS number
- Name
- Contact details
- 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.

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 and we will keep all information about you safe and secure.

The data relating to your code number (pseudo anonymised data) will be kept for up to 25 years and a copy of your consent form will be stored in the investigator's site file. Your contact details and consent form (the copy that the researcher will receive) will be kept until the end of the study and then destroyed. Your contact details and a copy of your consent form will be kept on a separate database to that for the study data (i.e. will not be linked to your medical data) and this will be destroyed at the end of the study. A copy of your consent form will also be kept in your medical notes and managed by the NHS.

Access to all data will be strictly controlled, and all current Data Protection Regulations will be followed.

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.

What are your choices about how your 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 GP. If you do not want this to happen, tell us and we will stop.

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.

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

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- Leaflet available from www.hra.nhs.uk/patientdataandresearch
- by sending an email to coat@soton.ac.uk, or
- by ringing us on 02381 550206
- by contacting the University of Southampton Data Protection Officer via email data.protection@soton.ac.uk

Details on how to contact the researchers:

If during the course of the study, you have any questions regarding your participation or would like study-specific information, please contact:

Central COAT study team

coat@soton.ac.uk

OR

Chief Investigator for the overall study

Professor Nick Francis
Professor of Primary Care Research
University of Southampton
nick.francis@soton.ac.uk

Trial sponsor
Address:
Research Governance Office
The University of Southampton
Building 37
Highfield Campus
Southampton
SO17 1BJ
Tel: 023 8059 5058
Email: rgoinfo@soton.ac.uk

In case of a complaint, please contact the COAT central study team, the Chief Investigator or the Trial sponsor and they can direct you to your local Patient and Liaison Service for advice.

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