Participant Information Sheet

C-LACE: Cefuroxime Levels After Caesarean Section

Full title of research study: understanding pharmacokinetic distribution of cefuroxime when given prior to caesarean section in body fat and blood.

Summary of the Participant Information Sheet:

Doctors and Pharmacists at Birmingham Women’s Hospital and the University of Birmingham, School of Pharmacy are investigating how the body mass index of the woman affects the concentration of the standard antibiotic (Cefuroxime) given to women prior to having a Caesarean section. They are particularly interested in the concentration of antibiotic in the blood and at the site of incision (tummy).

You have received this information sheet as you are scheduled to have a Caesarean Section at Birmingham Women’s Hospital and are eligible to take part in this study.

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it and for future research.

We will make sure no-one can work out who you are from the reports we write.

The information sheet tells you more about this study and what it involves.

This study is sponsored by University of Birmingham.

Please read the following information and if you have any queries, please discuss them with your friends, relatives or your hospital doctor or midwife. Please ask if there is anything that is not clear or if you would like more information.

**Why we are doing this research?**

Antibiotics are given prior to a Caesarean section (C-section) to reduce the chance of an infection following the procedure. At Birmingham Women’s Hospital, Cefuroxime is the antibiotic drug that is usually used (if a woman does not have a severe penicillin allergy, note that if you have a penicillin allergy then you are NOT eligible to participate in this trial). Every patient receives the same dose of antibiotic regardless of their height, weight and body mass index (BMI). Currently, approximately 1 in 10 women develop an infection following a C-section which can affect a woman’s recovery.

The likelihood of getting an infection increases with the woman’s body mass index and we want to know if this is related to the concentration of cefuroxime that is present in the blood and site of incision at the time of the C-section.

This research will assess whether the same dose of the antibiotic (cefuroxime) provides an adequate antibiotic coverage/concentration in all women; or whether women with a higher body mass index (BMI) would benefit from a higher dose of the drug. We will look at the concentration of antibiotic in blood and fat samples (within the incision) to see what level of antibiotic cover is reached in all women who participate.

The results from this study will be used to develop computer based models that better predict what dose would be required for a woman based on her height and weight. This may influence a change in dosing for the future, and in so doing reduce the rate of infection after a C-Section.

This research study is being undertaken as part of an educational qualification (a PhD) by Hanadi Alrammaal, at the School of Pharmacy at the University of Birmingham under the supervision of Dr Victoria Hodgetts-Morton. The local Principal Investigator is Dr Katie Morris, who is an obstetrician at Birmingham Women’s Hospital and a researcher at the University of Birmingham. The research project has been funded by the PhD grant for Hanadi Alrammaal which is paid by the Saudi government. The University of Birmingham are responsible for sponsoring the research.

**As a participant what do I have to do?**

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

This information will include your:

* Initials
* Name
* Contact details
* Body mass index (related to your height and weight)
* Details of the drugs used during your Caesarean Section
* General details about your health at the time of your Caesarean Section

People at Birmingham Women’s Hospital 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. Some of this information and the blood and fat samples will be transferred to the University of Birmingham, this information and the samples will use a coded number and there will be no identifiable information that is transferred to the University of Birmingham.

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.

We would also like your permission to take **three blood samples (each one of less than 10mL (two teaspoons)** and **two small samples of fat** from your tummy during your Caesarean section.

The first sample of blood will be taken at time of skin incision. After your operation, we will need to take another blood sample as close to the time of delivery as possible and the final blood sample will be taken in the recovery room. The samples will either be taken from a cannula inserted in your hand, the insertion of the cannula will be uncomfortable, or the samples taken by a very small ‘butterfly’ needle from your hand or foot. If the samples are taken from your foot this will be numb from the anaesthetic and will not hurt. We will discuss with you how best to take these samples in line with your personal preferences.

Just before your baby is delivered, we will ask your doctor to remove a small amount of the fat from under the skin on your tummy. This will be a very small amount (about the size of a 50p coin). During your C-section, you will have an anaesthetic so you should not feel any pain. Your doctor will deliver the baby and placenta then stich the womb. Just before your skin is stitched, your doctor will remove a second 50p sized sample of fat. Taking these small fat samples will take less than a minute each so the overall procedure is only a maximum of two minutes longer than without the fat samples.

By taking **these three samples of blood and two samples of fat**, we will be able to see how the Cefuroxime antibiotic concentration in your body changes during your operation. These samples will be collected into sample tubes and transported to the University of Birmingham. The analysis to determine the drug concentrations will be done at the University of Birmingham.

You will also be asked if you consent to any remaining tissue that is left over after this study is completed being used for other research at the University of Birmingham. This further research will require approval from a research ethics committee.

We would also like your permission to contact you by telephone between 30-40 days after your C-section to ask about whether you have had an infection as a result of the C-section. This telephone call will take a maximum of 15 minutes.

**How long do I need to take part for?**

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.

As well as the samples taken on the day of your C-Section we would like your permission to contact you by telephone once between 30-40 days after your C-section to ask a few questions and to find out if you have had an infection.

If we cannot contact you or you choose to stop taking part in the study, we would like to continue collecting information about your health from your medical notes. If you do not want this to happen, tell us and we will stop. We would like to look at your medical notes to see if there is any record of an infection as a result of your C-section. There are no additional Hospital visits involved in this study.

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.

**Will people know that the samples belong to me?**

The samples will be anonymised at the Hospital so the researchers at the University will not know who provided the sample. However, some details from your Hospital notes will be linked to the sample, using a study number. These include your: ethnicity; height; weight; location from where the fat sample was collected; times that samples were taken and additional details about the C-section procedure (anaesthetic used; dose of antibiotic used). This information will not include any details that can identify you.

**Am I eligible to participate?**

We will be seeking to recruit healthy women who are experiencing a normal pregnancy. We are interested in women with a range of body mass index values so that we know as much as possible about cefuroxime concentrations.

As this is a pilot study a limited budget prevents us from providing translation services for those participants unable to read and understand English. Participation has no direct benefits to participants thus exclusion on this basis does not affect the standard of care provided.

**Are there any risks or benefits?**

There are no direct health benefits to participants. The findings from this study will help us determine the appropriate antibiotic dosing strategy used in future for patients with a high BMI that need a C-section.

We do not believe that there are any major disadvantages or risks to taking part in this study. The additional procedures that you will receive are (i) insertion of an additional cannula for the taking of three additional blood samples and (ii) the removal of two samples of fat. The blood will be taken by a trained healthcare professional using standard methods to take blood; the risks associated with taking blood samples are minimal. The samples of fat will be taken from you whilst the skin is open for the C-section; you will be anaesthetized so will not feel any pain from this process. The amount of fat taken is small (about the size of a 50p coin) and this will not lead to visible differences to your body following your C-section.

Your doctor will explain all the risks that are associated with a C-section.

**What happens when the research project is completed?**

We will publish our results. This may take up to 3 years as it takes time to collect and analyse all the data that we need. We will not name any of the participants and all the data will be anonymised so no one will be able to identify you

We will also create a poster that describes this study that you (and other participants) can access once the work is complete. A link will be available on Dr Hannah Batchelor’s personal web pages: [www.hannahbatchelor.com](http://www.hannahbatchelor.com)

If you withdraw your consent to participate within 3 months of your C-section all data associated with you will be destroyed and the samples previously collected will be destroyed in accordance with the Human Tissue Act 2004 (HTA). A decision to withdraw after 3 months means that the data has already been analysed and anonymised it will not be possible to delete your data. All data will be anonymised in any publication and it will not be possible to identify you from this output.

**What if something goes wrong?**

If you wish to complain about any aspect of the way you have been approached or treated during the course of this study you should contact the following:

Birgit Whitman, the University of Birmingham’s Head of Research Integrity and Governance, who is an independent point of contact for research participants:

E-mail: researchgovernance@contacts.bham.ac.uk Phone: tel. 0121 415 8011

Alternatively, please contact the hospital’s Patient Advice and Liaison Service (PALS) Office on 0121 335 8226 or email BWC.formalcomplaints@nhs.net.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Birmingham or Birmingham Women’s Hospital but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).**Will my information be kept in private?**

Definitely, it is our main duty and priority to ensure that all your details will remain strictly confidential. Your name and any other personal details will be kept at the hospital. You will be given a study number, which will be recorded against your name and this record will be kept at the hospital, any documents or tissue leaving the hospital will only be identified with this study number.

The final page of this document provides full details of how your data will be managed.

**Will I be offered reimbursements?**

There will be no reimbursements offered as part of this study.

**Who has reviewed the research?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants’ interests. This study has been reviewed and given favourable opinion by the East Midlands (Leicester Central) Research Ethics Committee.

**Thank you…for your time and for considering participation in this study!**

**If you have any questions at all, please contact:**

Chief investigator: Dr Victoria Hodgetts Morton( v.a.h.morton@bham.ac.uk )

Local investigator: Dr Katie Morris (r.k.morris@bham.ac.uk)

Head of Research Governance and Integrity at the University of Birmingham: Dr Birgit Whitman researchgovernance@contacts.bham.ac.uk or on the phone: 0121 415 8011

If you would like independent advice about this study or have any complaints about this research, please contact the hospital’s Patient Advice and Liaison Service (PALS) Office on 0121 335 8226 or email BWC.formalcomplaints@nhs.net.

**Or you can note them here and bring this on the day of your appointment.**

**Appendix: Data Management Information**

In order to carry out the research project described above, we will need to collect information about you, and some of this information will be your personal data. Under data protection law, we have to provide you with very specific information about what we do with your data and about your rights. We have set out below the key information you need to know about how we will use your personal data.

The University of Birmingham Edgbaston, Birmingham B15 2TT is the data controller for the personal data that we process in relation to you.

The legal justification we have under data protection law for processing your personal data is that it is necessary for our research, which is a task we carry out in the public interest. We will not share your personal data with any third party.

The University takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. Our staff receive regular data protection training, and the University has put in place organisational and technical measures so that personal data is processed in accordance with the data protection principles set out in data protection law.

The University has an Information Security Management System based on ISO27001 with a range of controls covering the protection of personal information. Annual security awareness training is mandatory for staff and the University is accredited under the NHS Information Governance Toolkit, the Payment Card Industry Data Security Standard and is in the process of gaining Cyber Essentials Plus for defined services.

In relation to this project, data collected will be kept strictly confidential in a secure locked cupboard at the University of Birmingham where access is restricted to the research team.

***How long will my personal data be kept?***

Your data will be retained at the University of Birmingham for 10 years after the publication of the research outcomes and for 25 years at Birmingham Women’s Hospital. If you withdraw from the project, we will keep the information we have already obtained but, to safeguard your rights, we will use the minimum personally-identifiable information possible.

***Your rights in relation to your data***

* You may have the following rights in respect of your personal data:
* The right to access to your data (often referred to as a Subject Access Request).
* The right to rectification of inaccuracies in your data.
* The right to erasure of your data (in certain circumstances).
* The right to restrict processing of your data (in certain circumstances).
* The right to object to the processing of your data (in certain circumstances).
* The right to ask for your personal data to be transferred electronically to a third party.

However, your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the project, we will keep the information we have already obtained but, to safeguard your rights, we will use the minimum personally-identifiable information possible.

If you would like more information on your rights, would like to exercise any right or have any queries relating to our processing of your personal data, please contact:

The Information Compliance Manager, Legal Services, The University of Birmingham, Edgbaston, Birmingham B15 2TT

Email: dataprotection@contacts.bham.ac.uk Telephone: +44 (0)121 414 3916

If you wish to make a complaint about how your data is being or has been processed, please contact our Data Protection Officer.

Mrs Carolyn Pike, OBE, The Data Protection Officer, Legal Services, The University of Birmingham, Edgbaston, Birmingham B15 2TT

Email: dataprotection@contacts.bham.ac.uk Telephone: +44 (0)121 414 3916

You also have a right to complain to the Information Commissioner's Office (ICO) about the way in which we process your personal data. You can make a complaint using the ICO’s website.