Participant Information Sheet

STOPPIT-M study

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

STOPPIT-M is a study linked to the main STOPPIT-3 study which aims to look at the ways in which antenatal corticosteroids (ACS) work.

The STOPPIT-3 study aims to find out if the drug ACS given to women with a twin pregnancy prior to a planned birth of twins reduces breathing difficulties in the twin babies.

In the STOPPIT-M study we will aim to understand how the ACS work or do not work. We know that ACS can directly cross the placenta and reach the baby. We think that ACS may damp down the babies own 'stress response' systems and this could impact whether the babies have problems such as breathing difficulties and low blood sugar.

Why have I been invited to take part?

You have been asked to take part as you are participating in the STOPPIT-3 trial and planning to have a caesarean section for the birth of your twins.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you withdraw from STOPPIT-M, you can still continue to participate in STOPPIT-3. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

We are inviting women who are taking part in the STOPPIT-3 trial and have been treated with either ACS or a placebo (dummy drug) prior to the planned birth of their twins by a caesarean section to take part We are only asking women to take part if they have a planned caesarean section, so if you go into labour and deliver, we will not ask you to take part. If you decide to take part, we will ask you to sign a consent form.

At the birth of your babies, we will take blood samples from you and the babies' cord (about an egg cup full). We will collect some of the fluid that surrounded the babies in the womb and we will take a sample of the placenta. We will use the cord blood samples to measure the levels of the babies' stress hormone levels. We will also measure the stress hormones and levels of ACS in the other samples to further understand the babies stress responses. In a subgroup of babies recruited in Edinburgh, we will also collect a saliva sample before

and after a routine 'heel prick' blood test and we will sample a small section of the babies' hair. These samples will allow us to measure the babies' 'stress response' and overall stress hormone release. We will look at how these stress responses differ in babies who need help with their breathing in the short term, and whether there are differences in the babies development in the longer term.

What are the possible benefits of taking part?

Taking part will help create much needed evidence on the use of ACS prior to a planned birth of twins which will help women and babies in future. However, we cannot promise the study will directly help you or your babies. Information we obtain from your participation in the study may help inform on the future healthcare of other patients.

What are the possible disadvantages of taking part?

There are no disadvantages of taking part. We will only collect research samples after your routine clinical samples have been collected so that this will not impact your clinical care.

What if there are any problems?

If you have a concern about any aspect of this study please contact <insert name and contact details here> who will do their best to answer your questions.

In the unlikely event that something goes 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 NHS XXXX but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

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

You can withdraw from the study at any point. This will not affect your clinical care.

If you choose to withdraw from this study we ask you if we can continue to collect information on your and your babies' health through the main STOPPIT-3 trial. We would hope to continue to collect some information from your notes about your health and your babies' health. You will be asked if you agree to this. We think it is important to collect this information, so that we can find out if giving women with a twin pregnancy ACS has a positive impact on the health of mother and babies or not.

You can also withdraw from the study and request we collect no further data about and your babies' health. The data collected up to the point of withdrawal will still be used in the study.

What happens when the study is finished?

We will write a clinical study report, which may be used for publication and presentation at scientific meetings. All information in this report will be anonymised. These results will be uploaded to a publically accessible database within a year of the study ending. Most of the samples that we collect for this study will be used to carry out the analyses that we have planned to do. Any remaining samples will be stored within our Edinburgh Reproductive Tissue Biobank for a further 10 years. Any future use of the samples would require the researcher to gain additional ethical approval.

All data from the STOPPIT-3 and STOPPIT-M study will be kept for at least 25 years from the end of the study.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

Any details we have about you will be kept securely, with access restricted on a secure database managed by the University of Edinburgh Clinical Trials Unit (ECTU). This information will be used only to contact you about the study by doctors or researchers running this study.

We will not share any personal information, collected from the main STOPPIT-3 trial, held about you with any other organisation. With your permission, we would like to share anonymised information with other researchers, so we can learn more about the effects of ACS in twins.

We will inform your GP that you are taking part, with your consent.

Members of the clinical trial team such as doctors or researchers running this trial 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.

We will keep all information about you safe and secure.

Once we have finished the trial, we will keep the data collected for 25 years. This because there are laws regarding how long maternity records must be retained, and it means results from this trial can be checked in the future. We will write our reports in such a way that no-one can work out that you took part in the trial. **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.

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.

Where can you find out more about how your information is used?
You can find out more about how we use your information here:
www.hra.nhs.uk/information-about-patients/

- our leaflet available from **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by sending an email STOPPIT.Trial@ed.ac.uk or the Administrator:

Lorraine Adamson, email: L.D.Adamson@ed.ac.uk or the Data Protection Officer : Rena Gertz, email: Rena.Gertz@ed.ac.uk

What will happen to the results of the study?

The results of the study will be published in research journals and presented at scientific meetings.

We will also update you (the participant) a summary of the study findings through our trial website and other social media platforms. We do not expect the study results to be available until early 2026, and so we will update the website and social media sites with study progress. All information used for study updates and final results will be anonymous, and it will not be possible to identify individuals from any published material.

Who is organising and funding the research?

This study is organised and sponsored by the University of Edinburgh/NHS Lothian.

The study is being funded by the National Institute for Health Research (NIHR), Efficacy and Mechanism Evaluation Programme (EME) (Project: NIHR133388). The views and opinions are those of the authors and do not necessarily reflect those of the EME programme, NIHR or the Department of Health.

Who has reviewed the study?

Patients and the public have been involved in our development of protocols for collecting the proposed biosamples in this study and all have been considered acceptable. The key PPI representatives for the main STOPPIT-3 trial were also involved in the design of the study and contributed to the funding application.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. North of Scotland (2) Research Ethics Committee have reviewed the study. A favourable ethical opinion has been obtained. NHS Management Approval has also been given.

Researcher Contact Details

If you have any further questions about the study please contact <insert name> on <insert phone number> or email on: <insert email address>.

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact <insert contact details>.

Complaints

If you wish to make a complaint about the study please contact:

Adapt depending on research site <insert contact details>

NHS Lothian
Patient Experience Team

2 – 4 Waterloo Place, Edinburgh, EH1 3EG
feedback@nhslothian.scot.nhs.uk, 0131 536 3370

Participant ID: **Centre ID (if applicable)**

CONSENT FORM

Does infant hypothalamic-pituitary-adrenal (HPA) axis activity underpin respiratory morbidity and responses to antenatal corticosteroids (ACS) in later preterm and early term infants?

STOPPIT-M

Please **initial** box

1. I confirm that I have read and understand the information sheet (STOPPIT-M PIS DATE_VERSION) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected. ☐
3. I give permission for the research team to access my medical records for the purposes of this research study. ☐
4. I understand that relevant sections of my data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in the research. I give permission for these individuals to have access to my data and/or medical records. ☐
5. I understand that biological samples will be taken at the time of delivery (via caesarean section) and will include paired maternal and cord blood samples, amniotic fluid and placenta. ☐
6. I understand that samples may be taken from my baby/babies. If this is done, samples will include a saliva sample before and after a routine 'heel prick' blood test and a small section of the baby's hair. ☐
7. I agree to my General Practitioner being informed of my participation in the study. ☐
8. I understand that biological samples collected from me and my baby/babies during the study may be stored within the Edinburgh Tissue Biobank and accessed for research in the future. ☐
9. I agree to take part in the above study. ☐

Name of Person Giving Consent	Date	Signature
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1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record