

Parent Information Leaflet

Cooling in Mild
Encephalopathy
(COMET) trial



Neurological examination training
and assessment for clinicians

NIHR | National Institute for
Health and Care Research

Congratulations on the birth of your baby. We understand that this may be a difficult time for you. However, we think it is important for you to know about this study taking place in our neonatal unit.

This leaflet has two parts:

Part 1 tells you the purpose of this study and what will happen and what it will involve.

Part 2 gives you more detailed information about how we will use your data.

One of our team members will go through the information sheet with you and answer any questions you have.

PART 1 (STUDY DETAILS)

Why are we doing this study?

Our neonatal unit is participating in a large national study led by researchers at Imperial College London evaluating cooling therapy for babies with mild hypoxic ischemic encephalopathy or HIE. It happens when the unborn baby's brain

does not receive enough oxygen or blood flow around the time of birth.

By doing a careful clinical neurological assessment soon after birth experienced doctors can categorise the babies with HIE into either mild or moderate or severe HIE.

This categorisation is important as it will help doctors to decide what treatment to give.

A group of neonatal brain experts based at Imperial College London is studying if the use of artificial intelligence on analysis of the neurological assessment of babies soon after birth is useful in assessing brain injury. It is for this reason that we invite you to consider getting involved.

What is involved in participating in this study?

Your baby would have a neurological assessment by a doctor soon after admission to the neonatal unit, and a video of this assessment will be recorded. This examination is usually performed by

a doctor already trained and certified by neonatal neurology experts at the Imperial College London. Your baby will also have a brain wave study (also known as an amplitude integrated electroencephalogram or aEEG) soon after admission to the neonatal unit.

We request your permission to share this video and the aEEG with the researchers at Imperial College London for purpose of this research.

If you do not agree to share your baby's video, it will be immediately deleted.

Does my baby have to be involved?

Your baby does not have to be involved in this study if you do not want them to. If you do agree for your baby's data to be shared, you will be given this information sheet to keep and will be asked to sign a consent form. You will be given a copy of the signed consent form for your records.

Whether or not you agree for your baby to take part, this will not affect the standard of care you and your baby receive in any way.

What are the possible risks and benefits?

We do not anticipate any risks for your baby associated with this study and it does not change or delay the care your baby will receive.

All the data from your baby will be securely stored at Imperial College London and will be used only for purpose of this study and to provide feedback to clinical team, if appropriate.

While your baby won't benefit directly from this study, we hope it will help other babies in the future. If you wish to discuss this with someone independent from the study, you may contact the Patient Advice and Liaison Service (PALS) at this hospital.

What if relevant new information becomes available?

It is possible that new information may become available during the course of the study (4-5 years). It is unlikely that this will affect your baby's involvement with this study.

What happens when the research study stops?

We can send you a summary of the final results if requested.

What if there is a problem?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College London is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the local Principal Investigator.

The normal National Health Service complaints services are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.

PART 2 (DATA GOVERNANCE)

In this research study we won't use information from your baby's medical records. We will let very few people know your name or contact details, and only if they really need it for this study. These will include Imperial research Team members and support staff.

Everyone involved in this study will keep the data collated as part of this study, including your personal data, safe and secure. We will also follow all privacy laws and legislation that are relevant to the specifics of the study.

At the end of the study, we will save some of the data in case we need to check it and/or for future research. We will make sure no-one can work out who you are from the reports we write.

HOW WILL WE USE INFORMATION ABOUT YOU?

Imperial College London is the sponsor for this study and will act as the Data

Controller for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study is expected to finish in May 2029.

For more information / confirmation regarding the end date please contact the study team, see '**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED**' for contact information.

We will need to use information from your baby's medical record for this research project.

This information will include your initials, name and contact details and your baby's NHS number and name.

People within the College and study team (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact details) is accurate.

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 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.

As a university we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in

research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

- Imperial College London - “performance of a task carried out in the public interest”); Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London relies on “scientific or historical research purposes or statistical purposes

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation.

If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above).

Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the

study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad.

Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

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 because some research using your data may have already taken place and this cannot be undone.

- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital records and GP. If you do not want this to happen, tell us and we will stop. This will not affect any healthcare or support you may be receiving separately.
- 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 this could affect the wider study or the accuracy of data collected.
- 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:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to COMET@imperial.ac.uk, or
- by ringing us on 020 3313 2473.

COMPLAINT

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to COMET@imperial.ac.uk, or by ringing us on 0202 3313 2473.

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the

Imperial College London

Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.

What will happen to the results of the research study?

The results of the study will be made available to doctors and nurses caring for babies like yours across the world.

You and your baby will by no means be identified in any report or publications about the study. We can send you a summary of the final results, if requested.

Who is organising and funding the research?

The study will be run at several national sites. It is funded by the National Institute for Health Research. Imperial College London is the main sponsor. Doctors will not be paid for including you in the study, nor do participants receive payment.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a

Research Ethics Committee, to protect your interests.

This study has been reviewed and approved by the London - Bloomsbury Research Ethics Committee (REC) and Health Research Authority (HRA).

CONTACTS

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Thank you for reading this leaflet. and considering the study during this difficult time for you. If you would like to discuss this study and ask some questions, please ask the doctor or nurse looking after your baby.