IMPERIAL

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Parent Information Sheet

Cooling in Mild Encephalopathy (COMET) trial

We invite you to take part in a research study

- This research is being run by doctors and researchers from Imperial College London.
- This research is funded by the National Institute for Health and Care Research (NIHR).
- It's important for you to understand the study and what it will involve before you decide
- Please take time to read the following information carefully.
- You can choose if your baby takes part or not. This won't affect the care they receive.
- Please ask if you are unsure about anything
- If you decide to take part, you will get a copy of this information sheet and your consent form.

Important things that you need to know

- The term Hypoxic Ischaemic Encephalopathy describes the way a baby behaves (encephalopathy) after a lack of oxygen (hypoxic) and blood flow (ischaemic) to the baby's brain during birth. It is known as HIE for short.
- HIE can affect newborn behaviour in different ways. Some babies have mild problems and recover quickly, while others might experience moderate to severe difficulties.
- Babies with moderate to severe HIE are transferred to a neonatal intensive care unit (NICU) for a treatment called cooling therapy.
- Cooling therapy is effective in some but not all babies.
- We don't know whether cooling therapy works for babies with mild HIE

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How to contact us

If you have any questions about this study, please contact:

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1 Why are we are doing this study?

This trial is for newborn babies with mild Hypoxic Ischaemic Encephalopathy (HIE).

Babies with mild HIE often have short-term problems with their breathing, feeding and often are very irritable. Even though their brain activity looks normal, they usually need to stay in hospital for a few days. Most babies with mild HIE recover fully and quickly, but many have lower cognitive skills (thinking ability) at 2 years and may require special educational support at school.

The aim of this study is to find out if Cooling Therapy is better than keeping the baby at a normal body temperature for improving their cognitive ability (thinking skills) at 2 years of age.

What is Cooling Therapy?

Cooling Therapy involves carefully lowering a baby's temperature from the normal temperature of 37ºC to a temperature of 33.5ºC for the first 3 to 4 days of life. Cooling is started as early as possible after birth. Pain relief is given to prevent discomfort during cooling.

At the end of the treatment the baby's temperature is slowly returned to normal. This period of cooling gives the brain a chance to recover.

While Cooling Therapy does benefit babies with moderate or severe HIE and is used as standard treatment in the NHS, we do not know if this treatment benefits babies with mild HIE.

2 Why am I being asked to take part?

Soon after your baby was born, doctors checked your baby's brain activity and how your baby responds to sound, touch, and movement. These tests show that your baby has mild HIE. You have been invited to take part because your baby has been identified as a suitable participant for this study.

With your permission, a video of this examination will be shared with experts at Imperial College London to help with the study. About 426 babies from different hospitals will be in the study. It will take about five years to finish. Your baby's healthcare team can provide more details about the study and its current stage

3 What will happen to my baby if I take part?

If you choose to participate, you'll be asked to sign a consent form within six hours of birth. Afterwards, your baby will be randomly allocated to receive either Cooling Therapy (33.5°C) or to be kept at a normal body temperature (37.0°C) for 3 to 4 days. The purpose of this allocation is to understand which treatment is more effective for babies with mild HIE.

All babies in the study will receive the same standard care. If your baby is born at a non-cooling centre and is randomised to the cooling arm, they will be transferred to the nearest cooling centre (specialised neonatal intensive care unit; NICU) within 8 hours of birth for continued care. If your baby is randomised to the control arm, they will remain at the original hospital of birth.

Your baby may need an MRI scan before going home. An MRI (magnetic resonance imaging) is a safe and painless test that uses magnets and radio waves to create a detailed picture of the brain. This scan can help us understand your baby's brain development and their future needs. The doctors will discuss the results with you, including any unexpected findings.

We will collect information from your baby's medical records, including results from tests like aEEG/EEG (brain wave recordings), a brain ultrasound (which uses sound waves to create pictures of the brain), and routine blood tests.

What happens when the research study ends?

After your baby goes home, we'll stay in touch to follow their progress. We may contact you by email or phone to ask about your baby's development, including any visits to the doctor or hospital. When your baby is about two years old, we will assess their development. We will also review your medical records from pregnancy and ask for information about any problems you experienced during pregnancy.

We may request your permission for another assessment when your baby is of school age.

4 Do I have to take part?

No. Participation is voluntary. You have the right to choose whether or not to take part in the study. Your decision will not affect the standard of care you and your baby receive in any way.

If you choose not to take part, the care usually received by babies at your hospital will vary depending upon their guidelines, and this may or may not include cooling. Depending on your hospital's policy, your baby may still have the MRI scan and neurological assessment at two years of age.

5 Will my baby be okay?

Some babies with mild HIE do go on to make a full recovery. Other babies may have lower cognitive skills (thinking ability) at 2 years and may require special educational support at school.

What are the possible benefits of my baby taking part in the study?

All babies participating in this study will be closely monitored by experts in neonatal brain injury at a specialist centre, and detailed neurological assessment performed at 2 years of age.

At present, we do not know if a lower body temperature (33.5°C) for first three days is better than normal body temperature (37°C) for improving their cognitive ability at 2 years of age for babies with mild encephalopathy. We are doing this study to find out which treatment is better to help doctors to take the right decisions about the care of babies with mild encephalopathy in the future.

What are the possible disadvantages and risks of my baby taking part in the study?

If your baby is in the lower temperature group, there is a chance that this may lower the platelet (blood clotting) levels in your baby's blood. We will monitor the platelet levels of all babies with HIE and will administer platelet transfusions if required. Some babies may develop small bumps on their skin, which will eventually disappear without any consequence. Babies nursed under lower body temperature are likely to require a longer hospital stay than those nursed under normal body temperature, by an additional day or two.

What if new information about mild HIE becomes available?

It's possible that new information about mild HIE might be discovered during the study. While this is unlikely to affect your baby's involvement, we will let you know if the study needs to be stopped early because of new findings.

6 Can I stop taking part?

Your baby's participation in this study is entirely voluntary. You are free to decline for your baby to enter or for your baby to withdraw from the study at any time without having to provide a reason. If you choose to do this, it will in no way affect your baby's future medical care.

We may ask you for your consent to use the information already collected so far, or as a part of standard clinical care, for research purposes.

What happens when the research study stops?

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

7 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.

8 What will you do with my data?

In this research study we will use information from yours and your baby's 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. These will include Imperial research Team members and support staff.

Everyone involved in this study will keep your data safe and secure. 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 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, NHS number, name, contact details, test results and medical history. 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 0207594 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 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 reports or publications about the study. We will send you a summary of the final study results at the end of study.

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 London - Bloomsbury Research Ethics Committee.

Contact for further information

Please use the contact details listed on the first page of this document.

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.