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Short Parent Information Leaflet

Cooling in Mild Encephalopathy (COMET) trial

To be given to parents of potential study participants

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 particular study, taking place in our neonatal unit. This short leaflet explains why the research is being done and what it will involve.

One of our team members will go through a more detailed information sheet with you and answer any questions you have, should you wish to participate.

What is this study about?

We are looking at babies who have had some problems at the time of birth, which we suspect has resulted in a mild brain injury.

Although these babies improve within few days and get discharged home, many have lower cognitive skills (thinking ability) at 2 years and over a third require special educational support at school.

The aim of this study is to find out if a lower body temperature (33.5^{0}C), also known as cooling therapy / whole body hypothermia), for first 3-4 days is better than normal body temperature (37^{0}C), also known as targeted normothermia, by reducing their brain injury and improving long-term health.

What is involved in participating in this study?

If you agree to participate, your baby will be randomly placed in one of the following two groups, within six hours of birth:

1) nursing at normal body temperature (37^{0}C) for 3-4 days using incubators or servo-controlled warmers (targeted normothermia) or
2) nursing at low body temperature (33.5^{0}C) for 3-4 days using a cooling blanket (cooling therapy / whole body hypothermia).

The aim of this part of the study is to examine if low body temperature for 3-4 days reduces brain injury, when compared with normal body temperature for 3-4 days.

We will also collect a small amount of blood (third of a teaspoon) from your baby during the study. First, soon after birth, during the treatment, and again at 3-4 days, to examine their response to different core body temperature.

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What are the possible benefits of my baby taking part?

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.

Studies have shown that babies who participate in clinical trials generally have better outcomes, irrespective of the study group. 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?

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 neonatal encephalopathy and will administer platelet transfusions if required.

Some babies may develop small bumps on their skin, which will eventually disappear without any consequence. It is also possible that participating in the study may increase the hospital stay of your baby by a day or two.

Does my baby have to take part?

Your baby does not have to take part in this study if you do not want them to be involved. If you do agree for your baby to take part, 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.

Who is organising and funding the research?

The study will be run at several national and international sites. It is funded by the National Institute for Health Research. Imperial College London is the main sponsor. This study has been reviewed and approved by London - Bloomsbury Research Ethics Committee.

Please do not hesitate to ask if you have more questions.

CONTACTS

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