Patient Information Leaflet

Study title: BiB (Babies in Blankets) Trial - A randomised controlled trial comparing the use of a biliblanket to no treatment, in term infants who developed physiological jaundice

Principal investigator's name:	**Dr Aoife Branagan** **Dr Rachel Mullaly**
Principal investigator's title:	**Registrar in Neonatology**
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Consultant co-investigator's name:	**Prof J. Miletin**
Consultant co-investigator's title:	**Consultant Neonatologist**

You are being invited to take part in a research study to be carried out at the Coombe Women and Infants University Hospitals by Dr's Aoife Branagan and Rachel Mullaly, and Prof. J Miletin.

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study. If you decide not to take part it won't affect your future medical care.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

Why is this study being done?

Jaundice is a common problem developed in otherwise well new-born babies It occurs when there is yellowing of the skin due to accumulation of bilirubin due to the immature liver being unable to clear it. In low amounts it causes no harm to babies. Some babies will need treatment for their jaundice because of the risk of long-term problems related to very high bilirubin levels. This is done by phototherapy – the use of overhead lights to help decrease bilirubin levels in the body. Treatment with phototherapy requires a baby to be admitted to the neonatal unit and being separated from their mother on the post-natal ward.

A biliblanket is a type of phototherapy which can be used on the post-natal ward by putting the light inside the clothing, usually before they reach the level where phototherapy is needed. However, there is little research to show if this is effective in avoiding the need for phototherapy.

This research study is taking place to find out if using a biliblanket on the post-natal ward in babies who are coming close to the need for phototherapy will help babies avoid admission to the neonatal unit for phototherapy.

Why am I being asked to take part?

You, and your baby are being asked to participate in this study because your baby has developed jaundice and is nearing the 'treatment line' for phototherapy.

How will the study be carried out?

The study is being carried out on the post-natal ward in the Coombe. There will be 150 babies in total participating.

Babies who take part in the study will be divided randomly into two groups.

In the first group, the intervention group, babies will be put on a biliblanket on the post-natal ward. The baby will have their bilirubin levels measured every 6 – 12 hours until the jaundice level decreases enough to not require monitoring, or it rises to a level needing overhead phototherapy in the neonatal unit.

In the second group, the control group, babies will stay on the post natal ward and have usual care ie no biliblanket. They will have bilirubin level monitored until it has falled to a safe level and monitoring is stopped or it increases and they require phototherapy.

What will happen to me if I agree to take part?

If you agree to participate, your baby will be randomly allocated to one of the study groups – intervention (treatment with a biliblanket) or control (no biliblanket treatment). In both groups infants will have bilirubin levels monitored by blood sample, usually taken from a heelprick but sometimes from a vein. Babies who do not participate will also need to have bilirubins levels monitored in the same way.

Babies will stay on the post-natal ward with their mother for the duration of the study, however babies in both groups (or not participating in the study) may needed to be admitted to the neonatal unit for phototherapy or for other reasons.

After the baby has been discharged home, the research team will use your babies medical notes to obtain information on the treatment and follow up they required for their jaundice.

What other treatments are available to me?

Because your baby has developed jaundice and is nearing the treatment line, they will require monitoring for this and may require treatment for this. The decision as to whether it is best to use a biliblanket for your baby will be made by a neonatal doctor who will also decide how often to monitor the bilirubin level. Treatment and follow up will be very similar to that of babies involved in the study as we need to follow all babies to see if they require phototherapy for jaundice.

What are the benefits?

Use of a biliblanket may decrease the need for phototherapy for neonatal jaundice – therefore decreasing the chance of separating mother and baby due to admission to the neonatal unit.

What are the risks?

Using a biliblanket may not result in avoiding phototherapy and a baby may need admission to the neonatal unit after treatment. They may also need to be admitted if they develop other issues separate to jaundice.
Using a biliblanket may slowly decrease bilirubin levels, so keeping a baby on the postnatal ward with the mother but prolonging length of stay for monitoring or ongoing treatment.
A baby who is randomly assigned to the control group will not be treated with a biliblanket – undergoing usual care.

Is the study confidential?

Medical records will be accessed by the research team to compile results of the study.
All information collected will be anonymised after collection and will be kept private and confidential.
The results of the study will be collated and presented or published in the medical literature. However, you or your baby will not be identifiable from any of the resulting presentations or publications.
Neither the information collected from this study or the samples taken will be kept or used for any other purpose, including use in future research studies.

Data Protection

1. We will be using your personal information in our research to help identify the best way to treat jaundice in neonates.

2. Data collected will only be used for the purpose of the research study under the regulation of the General Data Protection Regulation 2016.

3. Only members of the research team will have access to the raw data.

4. Data will be stored for the duration of the project – less than 2 years.

5. Participants in the study can withdraw at any point, including after discharge from hospital. This can be done by discussion with a member of the research team listed above or by talking to the neonatal doctor treating your baby.

6. You have a right to lodge a complaint with the Data Protection Commissioner.

7. You also have a right to request access to your babies data and receive a copy.

8. Data subjects have a right to restrict or object to processing of data e.g. the data subject doesn't want their data shared but doesn't mind having it collected and stored.

9. The data subjects have a right to have any inaccurate information about them corrected or deleted.

10. The data subjects have a right to have their personal data deleted, unless their request would make it impossible or make it very difficult to conduct the research. e.g. they wanted to delete their data at the end of a research project just before it is due to be published.

11. The data subjects have a right to data portability, meaning they have a right to move their data from one controller to another in a readable format.

12. The data subjects have a right to object to automated processing including profiling if they wish.

Where can I get further information?

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future.
If you need any further information now or at any time in the future, please contact:

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