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Does the use of a biliblanket prevent the need for phototherapy in newborns over 24 hours of age with a gestation over 35 weeks who have developed physiological jaundice near to the treatment requirement line?

Submission date
05/01/2022

Recruitment status
No longer recruiting

Registration date
08/01/2022

Overall study status
Completed

Last Edited
01/07/2026

Condition category
Neonatal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Jaundice is a common and usually harmless condition in newborn babies that causes the skin and the whites of the eyes to turn yellow. In most cases, there is no underlying cause and it is therefore called 'physiological jaundice'. It occurs in well, term infants due to the accumulation of bilirubin (an orange-yellow pigment). Some infants must undergo treatment for jaundice with the use of phototherapy (light therapy) due to the risk of long-term consequences of high levels of bilirubin. Treatment of jaundice requires admission to the neonatal intensive care unit and therefore separating mother and baby. The biliblanket is a phototherapy device that is available for use on the ward. However, there is no evidence as to whether the use of a biliblanket on the ward before the requirement for phototherapy decreases the risk of needing admission for phototherapy. There is also concern that the use of a biliblanket may slow the rise of bilirubin, resulting in prolonged inpatient stays. The aim of this study is to find out whether the use of a biliblanket prevents the need for phototherapy in infants with jaundice.

Who can participate?
Infants over 35 weeks gestational age and 24 hours of life who have developed neonatal jaundice but have not reached a level requiring treatment with overhead phototherapy.

What does the study involve?
Infants are randomly allocated to receive treatment with a biliblanket or to not receive treatment. Both groups will be monitored closely for the need for phototherapy treatment. Both groups will have their bilirubin levels monitored every 12 hours until they require overheard phototherapy treatment or they reach a safe level for their age and gestation.

What are the possible benefits and risks of participating?
There are no benefits to individual participants. There is some risk of prolonged length of stay with the use of a biliblanket. No other risks are known.

Where is the study run from?
Coombe Women and Infants University Hospital (Ireland)

When is the study starting and how long is it expected to run for?
April 2020 to December 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Aoife Branagan
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Contact information

Type(s)
Public

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Additional identifiers

Study information

Scientific Title
Utilization of a biliblanket to decrease the need for overhead phototherapy and admission to a special care baby unit - a randomised control trial (BiB trial)

Acronym
BIB

Study objectives
Neonatal jaundice is a common condition affecting newborn infants, occuring in well, term infants due to the accumulation of bilirubin. Some infants must undergo treatment for jaundice with the use of phototherapy due to the risk of long-term consequences of high levels of bilirubin. Treatment of jaundice requires admission to the neonatal intensive care unit and therefore separating mother and baby. The biliblanket is a phototherapy device which is available for use on the ward. The hypothesis is that treatment with a biliblanket on the postnatal ward, in infants who have a serum bilirubin level approaching the treatment line on a standardised nomogram, will decrease the need for overhead phototherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/08/2020, Research Ethics Committee, Coombe Women and Infants University Hospital (Cork St, Dublin 8, Ireland; +353 (0)1-4082000; rec@coombe.ie), ref: 21-2020

Primary study design
Interventional

Study design
Single-centre two-armed randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neonatal physiological jaundice

Interventions
Randomisation will occur on receipt of informed consent. A computer-generated random number list will be used, prepared by an investigator with no clinical involvement in the trial. Sequence generation will be stratified by gestational age – under 37 weeks and over 37 weeks. Once generated the randomisation lists will be sealed in opaque envelopes. Once the patient is consented to enter the trial, the investigator will open the next sequential opaque envelope in the correct strata and provide the allocated interventions. In the case of multiple births, each infant will be individually randomised. Blinding of parents or research staff will not be possible due to the nature of the intervention.

The intervention group will be treated with a biliblanket system on the postnatal ward. The control group will have standard care (no biliblanket). Both groups will have serum bilirubin levels monitored every 12 hours until they require overheard phototherapy treatment or they reach a safe level for their age and gestation.

After receipt of a serum bilirubin level near the treatment line (less than 35 umol/l below treatment line for age taken) when compared with age on an appropriate treatment nomogram, the parents or guardians of the infant will be approached for informed consent by a member of the research team or a neonatal doctor.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Biliblanket system

Primary outcome(s)
Need for overhead phototherapy (binary [yes/no]): admission to the neonatal unit for phototherapy measured by a chart review at discharge from hospital and time of maximum follow-up (6 weeks of age)

Key secondary outcome(s)
Length of hospital stay (continuous) measured in days by chart review at time of maximum follow-up (6 weeks of age)

Completion date
01/12/2022

Eligibility

Key inclusion criteria
1. Infant greater than 24 hours of age on post natal ward
2. Greater than 35 weeks gestation
3. Suspected physiological jaundice
4. Serum bilirubin less than 35 umol/l under the phototherapy line

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Jaundice under 24 hours
2. Infants admitted to the neonatal unit for any reason
3. Infant less than 35 weeks gestation
4. Known Direct Coombs Test (DCT) positive jaundice at time of recruitment

Date of first enrolment
01/09/2020

Date of final enrolment
01/08/2022

Locations

Countries of recruitment
Ireland

Study participating centre
Coombe Women and Infants University Hospital
Cork St
Dublin 8
Dublin
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Sponsor information

Organisation
Coombe Women & Infants University Hospital

ROR
https://ror.org/00bx71042

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

Data will be available on request from the investigators (Dr A Branagan [branagaa@tcd.ie] or Prof. J Miletin [jmiletin@coombe.ie]). Anonymised data will be made available after analysis in Excel format. The data will be made available on request for the purpose of meta-analysis. As it is fully anonymised it can be shared by email.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/06/2026	01/07/2026	Yes	No
Participant information sheet	version 1	17/06/2020	07/01/2022	No	Yes
Protocol file			07/01/2022	No	No