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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**
07/01/2022

**Condition category**
Neonatal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## 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

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Public

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
Nil known

# 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

### Study design
Single-centre two-armed randomized controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
See additional files

## 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

## Primary outcome measure
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)

## Secondary outcome measures
Length of hospital stay (continuous) measured in days by chart review at time of maximum follow-up (6 weeks of age)

## Overall study start date
01/04/2020

## 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

### Age group
Neonate

### Sex
Both

### Target number of participants
100

### 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

### Sponsor details
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+353 (0)14082000
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### Sponsor type
Hospital/treatment centre

### Website
https://www.coombe.ie

### ROR
https://ror.org/00bx71042

## Funder(s)

### Funder type
Other

### Funder Name
Investigator initiated and funded

## Results and Publications

### Publication and dissemination plan
The findings of this study will have important implications for infants and families and the researchers will aim to publish the data and disseminate it as widely as possible. Once complete they will submit their findings for presentation at national and international scientific meetings and for publication in a peer-reviewed scientific journal.

### Intention to publish date
31/12/2022

### 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? |
|---|---|---|---|---|---|
| Participant information sheet | version 1 | 17/06/2020 | 07/01/2022 | No | Yes |
| Protocol file | | | 07/01/2022 | No | No |