BiB Trial (**B**abies **i**n **B**lankets)

Utilization of Biliblanket to Decrease Need for Overhead Phototherapy and Admission to Special Care Baby Unit - a Randomised Control Trial (BiB Trial)

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Protocol

Research Question

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

PICO

Population

Inclusion criteria - Infant greater than 24 hours of age on post-natal ward

Infants 35+ weeks gestation

Suspected physiological jaundice

SBR less than 35umol away from treatment line for hours of life

Exclusion criteria – Under 35 weeks of gestion

Jaundice (requiring treatment) less than 24 hours of age

Known DCT positive jaundice

Admission to Neonatal unit for another reason

Inability to speak English

Intervention

Biliblanket system on post-natal ward

2 systems in use: "Biliblanket plus high output phototherapy system" – Ohmeda medical (CE 0086)

"Bili-Therapy Pad type" – ATOM medical (CE0123)

Control

No biliblanket

Outcome

Primary - Need for phototherapy (conventional overhead phototherapy in SCBU)

Secondary – length of hospital stay (from time of randomisation)

Method/Design

Trial design - The trial is a single centre two-armed randomised controlled trial. The intervention group will be treated with a biliblanket system on the post-natal 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. A safe level is defined as serum bilirubin level 50umol or further from the treatment line.

Ethical approval – Ethical approval will be sought from the Research Ethics Committee in the CWIUH

Eligibility and Consent – After receipt of a serum bilirubin level near the treatment line (less than 35umol/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. The investigator will explain the study fully to the patient's parent(s)/guardian(s) using the Patient Information Sheet. If English is not their first language, they will be offered the opportunity to have an interpreter or support person present while the study is explained. Parents will be informed that they may withdraw their child from the study at any time should they wish; and that a decision not to consent their child's participation in the study or to withdraw their infant from the study once enrolled will not affect their infants access to the best available care at the CWIUH. Consent forms will be kept securely, and a copy will be provided in the patients' chart. Fully informed written consent will be obtained prior to enrolment.

Randomisation and Allocation Concealment - 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(s), doctor on duty or ANP 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 – Blinding of parents or research staff will not be possible due to the nature of the intervention.

Methods

Infants will be randomised after having an SBR sample which is 'near' the treatment line for their age (35umol or less from the treatment line on a treatment nomogram. Both groups will have SBR samples taken every 12 hours until they cross the treatment line and require phototherapy, or until

they are deemed to be at a safe level (more than 50umol) from the line and suitable for discharge home. Infants in the control group may also be discharged for repeat sample as an outpatient if deemed appropriate. The biliblanket group will have a rebound sample taken 8 hours after discontinuation of the blanket.

Sample Size Calculation

A retrospective chart review of infants who had serum bilirubin levels measured on the post-natal ward over a two month period was undertaken. Over this period 31 infants had serum bilirubin level less than 40umol under the treatment line for their age. 35% of these required phototherapy. We assume a minimally important clinical difference of 25%, reducing need for overhead phototherapy to 10% of these infants. To detect a difference of 25% between intervention and control groups with 80% power and alpha of 0.05, 51 patients would be required in each arm, 102 patients in total (Fisher's Exact Test).

Confidentiality

We will record data that is routinely collected for each infant in their medical records as part of their routine care. Participation in the study will not necessitate extra investigations or intervention over and above those indicated as part of their routine care. The data will be recorded on dedicated Case Report Forms (CRFs). These CRFs will not contain identifying information of individual infants and will be stored securely. Data which is extracted from these CRFs will be anonymised and entered into databases on password protected computers.

Conflicts of Interest

We have no conflicts of interest to declare.

Findings of this study

The findings of this study will have important implications for infants and families and we will aim to publish the data and disseminate it as widely as possible. If we receive ethical approval to proceed with this study it will be registered with the International Standard Randomised Controlled Trials Number Register (http://www.controlled-trials.com/isrctn/). Once complete we will submit our findings for presentation at national and international scientific meetings and for publication in a peer-reviewed scientific journal.

Consort Diagram