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Home phototherapy device in a hospital setting

Submission date
04/04/2015

Recruitment status
No longer recruiting

Registration date
28/04/2015

Overall study status
Completed

Last Edited
28/04/2015

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
Jaundice in new-born infants is a common condition caused by excess of bilirubin in the body. Jaundice affects more than half of all new-born infants and many of them require phototherapy. Phototherapy helps get rid of excess of bilirubin. Jaundiced infants needing phototherapy have to either stay longer in the hospital or go back to hospital. Hospitalisation is expensive and disrupts breast-feeding and infant-mother bonding. Many paediatricians have been recommending home phototherapy to avoid hospitalization. The aim of the study is to assess how well a phototherapy device (PEP Bed) works in hospital before we recommend it for use at home.

Who can participate?
Term and near- term infants with onset of jaundice in the first week of life and needing phototherapy.

What does the study involve?
Participants are randomly allocated to one of two groups: conventional phototherapy or phototherapy with PEP bed device. Although PEP Bed phototherapy device is designed for home use, in this study phototherapy is provided in the hospital itself. Serum bilirubin levels and duration of phototherapy are measured. Babies are monitored for any side effects of phototherapy including skin rash, dehydration, temperature variation or eye discharge. Headache, irritability, eye glare and giddiness are also noted.

What are the possible benefits and risks of participating?
There are no immediate benefits. However in the future jaundiced infants may be offered the option of home phototherapy. This will help establish breast feeding early and affects infant-mother bonding positively. Home phototherapy will also cut down the cost of treatment.
There are no foreseeable risks involved as phototherapy is a safe intervention and has been in use for over 50 years. The possible risk with a new phototherapy device is the infant needing phototherapy for a longer duration if the device is less effective. Infants on any type of phototherapy are at risk of temperature variation, they may have increased water loss from skin and may develop a temporary skin rash.

Where is the study run from?
KK Women's and Children's Hospital, Singapore.

When is the study starting and how long is it expected to run for?
September 2011 to August l 2013.

Who is funding the study?
Two new phototherapy devices made available by United BMEC Pte Ltd, Singapore.

Who is the main contact?
Dr Ashwani Bhatia

Contact information

Type(s)
Scientific

Contact name
Dr Ashwani Bhatia

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Evaluation of efficacy and safety of PEP Bed home PhotoTherapy device in a hospital setting

Acronym
PEPBed PT

Study objectives
How effective and safe is the use of home phototherapy device in comparison to a conventional phototherapy device?

Ethics approval required
Old ethics approval format

Ethics approval(s)
SingHealth Centralised Institutional Review Board, 02/09/2011, reference 2010/680/E

Study design

Term and late preterm infants with neonatal jaundice needing phototherapy were randomized to conventional phototherapy or PEP Bed phototherapy.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Neonatal jaundice in term or late preterm infants in the first week of life.

Interventions
Phototherapy by conventional phototherapy device or PEP Bed phototherapy device

Intervention Type
Device

Primary outcome(s)
Rate of decline in serum bilirubin (SB) level.
SB levels were taken up to 12 times hourly until the level was at or below “Off-Phototherapy” level. Rate of decline in SB was measured in each neonate by dividing the difference in levels of SB by hours of phototherapy given to the neonate. For example, case 1 had SB1 (230µmol/L) at the start of phototherapy, SB2 (195µmol/L) after 12 hours (Phototherapy continued) and SB3 (180µmol/L) level was below Off-Phototherapy level. Phototherapy was discontinued after 24 hours. Rate of decline in SB in this case is SB1-SB3 divided by 24 i.e., 230-180 divided by 24 = 2.08 µmol/L/hour.

Key secondary outcome(s))
Duration of phototherapy.
The nurses looking after the neonates were asked to feedback on their personal experience on a Likert scale whether they experienced any headache, irritability, giddiness, vertigo, eye glare or nausea.

Completion date
01/08/2013

Eligibility

Key inclusion criteria
Term or late preterm (gestational age 35 weeks or more, birthweight 2000 to 4000 grams) with onset of neonatal jaundice on day 2 to day 7 of life and needing single blue phototherapy.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Infants with jaundice needing double or intense phototherapy
2. Hemolytic Jaundice
3. Blood group incompatibilty
4. Glucose-6-phosphate dehydrogenase deficiency

Date of first enrolment
25/10/2011

Date of final enrolment
15/04/2012

Locations

Countries of recruitment
Singapore

Study participating centre
KK Women's and Children's Hospital
100 Bukit Timah Road
Singapore
229899

Sponsor information

Organisation
KK Research Centre

ROR
https://ror.org/0228w5t68

Funder(s)

Funder type
Research organisation

Funder Name
KK Women’s and Children’s Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request