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The effect of abdominal massage applied on term newborns receiving phototherapy on transcutaneous bilirubin level

Submission date
01/10/2019

Recruitment status
No longer recruiting

Registration date
08/11/2019

Overall study status
Completed

Last Edited
18/02/2021

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
Hyperbilirubinemia is a condition in which there is too much bilirubin in the blood. When red blood cells break down, a substance called bilirubin is formed. Babies are not easily able to get rid of the bilirubin and it can build up in the blood and other tissues and fluids of the baby's body. Newborn massage is one of the complementary treatments that can be used to lower bilirubin levels. Bilirubin is removed from the body by defecation and abdominal massage increases the bowel movement frequency of the newborn infants.
Therefore, this study has planned to determine the effect of abdominal massage intervention on term newborn infants receiving phototherapy on transcutaneous bilirubin levels as a randomized controlled trial.

Who can participate?
Newborns with hyperbilirubinemia who are undergoing phototherapy treatment

What does the study involve?
Participants will be randomly allocated to either receive standard care or standard care with the addition of abdominal massage for two days

What are the possible benefits and risks of participating?
The newborn ınfants who participating the study is undertaken phototherapy and have hyperbilirubinemia. The massage intervention is thought to reduce bilirubin by accelerating defecation. This is the primary benefit of the study. Also, this massage intervention can be taught to families and can be used to relieve the infant, to prevent constipation, and to relieve it emotionally. This can be thought the secondary benefit of massage. Since the intervention does not involve an invasive procedure, it is considered that there is no risk because no drug is administered

Where is the study run from?
Mega Medipol University Hospital, Turkey

When is the study starting and how long is it expected to run for?
October 2019 to September 2021 (updated 18/02/2021, previously: March 2020)

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
10840098-604.01.01-E.29907

Study information

Scientific Title
Comparison of bilirubin levels and physiologic signs according to abdominal massage intervention on term newborn infants in phototherapy: randomized clinical trial

Study objectives

H1. The transcutaneous bilirubin levels of term infants who applied abdominal massage are lower than who do not apply
H2. The number of bowel sounds of term infants who applied abdominal massage are more than who do not apply
H3. The heart rates of term infants who applied abdominal massage are lower than who do not apply
H4. The level of Oxygen saturations of term infants who applied abdominal massage is higher than who do not apply

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/07/2019, Medipol Mega University Hospital Ethical Committee (Medipol Mega Üniversitesi Hastanesi Etik Kurulu; Kuzey Kampüsü Kavacık Mah. Ekinciler Cad. No.19 Kavacık Kavşağı – Beykoz 34810 İstanbul, Turkey; ilknurfil@medipol.edu.tr; +90 444 85 44 – 5137), ref: 10840098/604.01.01-E.29907

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Hyperbilirubinemia, Jaundice

Interventions
This study has planned to determine the effect of abdominal massage intervention on term newborn infants receiving phototherapy for hyperbilirubinemia on transcutaneous bilirubin levels.

Baseline measures of transcutaneous bilirubin, SpO2, heart rate, bowel movement sounds will be taken

Experimental Group: Abdominal massage will be applied for 2 days, at least with 6 hours intervals 3 times a day for 6 sessions as 5 min for each session by the nurse who has a massage certificate

Abdominal Massage Intervention Steps
First step: Before the massage, the researcher will wash her hands and use the baby lotion to provide lubrication during the massage.
Second step: After the abdominal massage will start from the right side of the infant’s abdomen, the fingers will be moved to the left side with slight pressure. The expert nurse who will do massage will move her hands from the abdomen to the inguen in a clockwise direction by applying slight pressure.
Third step: The infant’s legs will be lifted up. Gentle pressure will be applied to the infant’s

abdomen by helping abdomen muscles to relax. The nurse will lift up the infant's legs with her left hand by holding his/her ankles and apply slight pressure on his/her legs with her right hand. Fourth step: After it will be pressed gently with the hands, the circular movements will be applied from the right inguen to the left inguen and legs in a clockwise direction

Control Group: Standard hospital care

Both group's data will be recorded at the time when the phototherapy is interrupted and the baby will be allowed to rest for 5 minutes and then transcutaneous bilirubin level, sounds of bowel movements, oxygen saturation, and heart rate will be evaluated and recorded on the observation form. These measurements will be made 3 times a day at least 6 hours intervals. For the experimental group, the measurements will be recorded before massage intervention.

The participants will be randomised by the Urn method (selection at random of a coloured ball from a closed bag)

Intervention Type
Other

Primary outcome(s)
1. Serum bilirubin level; routinely check every 24 hours in the neonatal unit.
2. Transcutaneous bilirubin level; will check from forehead before starting phototherapy.
3. Oxygen saturation: will check from pulse oximeter before starting phototherapy mean value for one minute after relaxed for 5 minutes
4. Heart rate: checked from pulse oximeter before starting phototherapy mean value for one minute after relaxed for 5 minutes
5. Sounds of bowel movements: the bowel movements will auscultate from over all four quadrants, 1 minute for each quadrant, total 4 minutes.
6. Serum bilirubin measurement will be repeated at the 48th hour of phototherapy after the last massage session (6th Session) -at least 6 hours later - in newborns in the experimental group
7. In newborns in the control group, blood bilirubin measurement will be repeated at 48 hours of phototherapy

Key secondary outcome(s))
1. Feeding type (breastfeeding or formulated bottle feeding):
1.1 For the newborns who breastfeed:
1.1.1 Duration of breastfeeding (minute)
1.1.2 Test weight of infant (g)
1.1.3 Number of breastfeeding (number/day) will be recorded
1.2 For the newborns who formulated feeding
1.2.1 Duration of feeding (minute)
1.2.2 Number of feeding (number/day)
1.2.3 Amount of each feeding (ml)
2. For both groups, the number of feces will be recorded for 2 days on the observation form

Completion date
30/09/2021

Eligibility

Key inclusion criteria

1. Family willing to participate in the research
2. Birth between gestational weeks > 37 and <42
3. Birth weight >2500 and <4000 g
4. Postnatal first minute APGAR score >7
5. Phototherapy treatment for the first time

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
Physical examination of the newborn performed by the physician and decided to another health problem other than hyperbilirubinemia

Date of first enrolment
15/10/2019

Date of final enrolment
30/10/2021

Locations

Countries of recruitment
Türkiye

Study participating centre
Mega Medipol University Hospital
Tem Avrupa Oto Yolu
Bağcilar
Istanbul
Türkiye
34214

Sponsor information

Organisation
Biruni University

ROR
https://ror.org/01nkhmn89

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

Study Protocol, Statistical Analysis Plan, Informed Consent Form, will be available, beginning 9 months and ending 36 months following article publication from the corresponding author on reasonable request.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes