Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of Effectiveness and Side Effects of Single and Double surface Intensive Phototherapy on Neonatal Jaundice in Be’sat Hospital, Hamedan

Protocol summary

Study aim

The main purpose of the study: -Determining the Effect and Complications of High-Power Single and Double-Level Phototherapy in Nonconjugated Jaundice in Neonates Hospitalized in Be'sat Hospital, Hamadan Aims: -Determination and Comparison of the Effectiveness of Single and Double surface Intensive Phototherapy on Indirect Bilirubin Levels -Determination and Comparison of the Effect of Single and Double surface Intensive Phototherapy on Serum Calcium Level -Determination and comparison of the effect of Single and Double surface Intensive Phototherapy on platelet count - Determination and comparison of the effect of Single and Double surface Intensive Phototherapy on the length of hospital stay -Determination and comparison of the effect of Single and Double surface Intensive Phototherapy on the fecal excretion status - Determining and comparing the effect of Single and Double surface Intensive Phototherapy on Patient's body temperature - Determination and comparison of the effect of high-level and two-level high-power phototherapy on incidence of skin rash

Design

Prospective study, Randomized clinical trial

Settings and conduct

Neonates Ward of Be'sat Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Term healthy newborn; Age less than 14 days; Birth weight ≥ 2500 grams; nonmolytic hyperbilirubinemia; Serum total bilirubin concentration between 15-20 mg/dl Exclusive Breastfeeding Exclusion criteria: Asphyxia; Pre-term; Bilirubin encephalopathy; Sepsis

Intervention groups

In 1st group, treated only with single surface intensive phototherapy, 6 lamps of chamber irradiate at distance of 20-30 cm, angle of 0-180° In 2nd group, treated only with double surface intensive phototherapy, 12 lamps of chamber irradiate at distance of 20-30 cm, angle of 0-360°

Main outcome variables

Indirect bilirubin; Serum calcium level; Platelet count, Duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191203045595N1**
Registration date: **2019-12-16, 1398/09/25**
Registration timing: **prospective**

Last update: **2019-12-16, 1398/09/25**
Update count: **0**

Registration date

2019-12-16, 1398/09/25

Registrant information

Name
Shadi VEISI
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 81 3827 0172
Email address
shadiwaisi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Effectiveness and Side Effects of Single and Double surface Intensive Phototherapy on Neonatal Jaundice in Be’sat Hospital, Hamedan

Public title
Evaluation of Effectiveness and Side Effects of Single and Double surface Intensive Phototherapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy term infant, with non-hemolytic hyperbilirubinemia with total serum bilirubin between 15-20 mg/dl 1-14 days old
Exclusion criteria:
Asphyxia Pre-term
Age
From **1 day** old to **14 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients with any level of bilirubin were randomly divided into two groups of 75 each. The questionnaires were coded from 1 to 150 (from 1 to 75 for single-level phototherapy and from 76 to 150 for two-level phototherapy). After each infant is enrolled in the study, one of the numbers is identified by lot and the questionnaire is filled out during the intervention.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamedan University of Medical Sciences
Street address
Childrens's Ward, Be'sat Hospital, Shahid Beheshtti Blvd., Hamedan
City
Hamedan
Province
Hamadan
Postal code
6514845411
Approval date
2019-05-18, 1398/02/28
Ethics committee reference number
IR.UMSHA.REC.1398.167

Health conditions studied

1

Description of health condition studied
non-hemolytic hyperbilirubinemia
ICD-10 code
P59.9
ICD-10 code description
Neonatal jaundice, unspecified

Primary outcomes

1

Description
indirect bilirubin level
Timepoint
Before intervention and then every 24 hours until discharge
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Single Surface Intensive Phototherapy. Patients are placed inside a Tosan double surface intensive phototherapy machine that provides 180 degrees illumination from up, at a distance of 20-30 cm. treatment continues uninterrupted until reducing Bilirubin to less than 10mg/dl.
Category
Treatment - Other

2

Description
Intervention group 2: Double Surface Intensive Phototherapy. Patients are placed inside a Tosan double surface intensive phototherapy machine that provides

360 degrees illumination from a distance of 20-30 cm. treatment continues uninterrupted until reducing Bilirubin to less than 10mg/dl.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Be'sat Hospital
Full name of responsible person
Shadi Veisi
Street address
Shahid Beheshti Blvd.
City
Hamedan
Province
Hamadan
Postal code
6514845411
Phone
+98 81 3827 0172
Email
shadiwaisi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Saeid Bashirian
Street address
Vice Chancellor for Research and Technology, Hamedan University of Medical Sciences, Shahid Fahmideh Blvd, Mahdieh St.
City
Hamedan
Province
Hamadan
Postal code
6517838696
Phone
+98 81 3838 0717
Email
bashirian@umsha.ac.ir
Web page address
http://research.umsha.ac.ir/

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Shadi Veisi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
Children's Ward, Be'sat Hospital, Shahid Beheshti Ave., Hamedan
City
Hamedan
Province
Hamadan
Postal code
6517653318
Phone
+98 81 3827 0172
Fax
Email
shadiwaisi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mohammad-Kazem SABZEI
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Children's Ward, Be'sat Hospital, Shahid Beheshti Ave., Hamedan
City
Hamedan
Province
Hamadan
Postal code
6514845411
Phone

+98 81 3827 0172

Fax

Email

mk_sabzehei@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Shadi VEISI

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Children's Ward, Be'sat Hospital, Shahid Beheshti Ave., Hamedan

City

Hamedan

Province

Hamadan

Postal code

6517653318

Phone

+98 81 3827 0172

Fax

Email

shadiwaisi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Main outcomes information

When the data will become available and for how long

6 months after the publication of results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Meta-analysis

From where data/document is obtainable

Sending an Email to: mk_sabzehei@yahoo.com

What processes are involved for a request to access data/document

- Reviewing request - Obtaining permission from the Vice President of Research and Technology of the University - Sending data

Comments