

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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 \geq 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 Beheshti 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

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Shahid Beheshti Blvd.

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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

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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

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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

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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

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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