

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Changing Position on Bilirubin Levels in Term Healthy Neonates with Jaundice During Phototherapy

Protocol summary

Summary

Position changes are believed to increase the efficacy of phototherapy and Turning of infants during phototherapy for hyperbilirubinemia is practiced in many nurseries, especially in our country. However, there is little research evidence in support of this practice. The aim of this study is to determine the effect of routine turning on the total serum bilirubin concentration and on the duration of phototherapy, versus only supine position. Seventy full-term newborn infants with nonhemolytic hyperbilirubinemia [greater than or equal to 15 mg/dl] are studied. Neonates are enrolled in the study with the consent of appropriate ethic committee on research affair and the infant's parents/ guardians. Convenience sampling is performed and infants are randomly divided into two groups. In "turning group", changing from a supine to a prone position or vice versa is performed every 150 minutes. The "fix group" is kept in the supine position during the entire study period. Total serum bilirubin is obtained just prior to the initiation of phototherapy, 6, 12, 18, 24, 48 and 72 hours after phototherapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111063250N4**

Registration date: **2011-12-04, 1390/09/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-04, 1390/09/13

Registrant information

Name

Bahareh Bahman Bijari

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 34 1322 2250

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Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2011-11-21, 1390/08/30

Expected recruitment end date

2012-04-19, 1391/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Changing Position on Bilirubin Levels in Term Healthy Neonates with Jaundice During Phototherapy

Public title

The Effect of Changing Position on Bilirubin Levels in Term Healthy Neonates with Jaundice During Phototherapy

Purpose

Treatment

Inclusion/Exclusion criteria

All term infants weigh more than 2500 gr without congenital malformation with serum bilirubin level 15-23mg/dL are included. Exclusion criteria: age more than 10 days; ABO incompatibility hemolytic jaundice;

any signs of infection including sepsis; Serum total Bilirubin concentration above than 23 mg which considered for high intensity phototherapy or blood transfusion.

Age

From **3 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee for human research, Kerman university of medical sciences

Street address

Vice chancellor for research, Tahmasb Abad crossroad

City

Kerman

Postal code

Approval date

2011-11-06, 1390/08/15

Ethics committee reference number

k/90/227

Health conditions studied

1

Description of health condition studied

Neonatal jaundice

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Total serum bilirubin concentration

Timepoint

hours 6, 12, 18, 24 and 72

Method of measurement

mg/dL using Autoanalyzer

2

Description

duration of phototherapy

Timepoint

hours 6, 12, 18, 24 and 72

Method of measurement

hour

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: changing baby position every 150 minutes

Category

Other

2

Description

Control group: fix supine position during the study

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipoor Hospital

Full name of responsible person

Street address

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpoor Afshar

Street address

vice chancellor for research, Tahmasb abad crossroad

City

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Kerman University of Medical sciences

Full name of responsible person

Dr Bahareh Bahman Bijari

Position

Neonatal fellowship/ professor

Other areas of specialty/work**Street address**

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Full name of responsible person

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Position

General practitioner

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty