

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

The efficacy and safety of white plastic cover around phototherapy unit in term jaundiced neonate: A randomized controlled trial

Protocol summary

Summary

The purpose of this study was to evaluate the effect of white plastic cover around the phototherapy equipment on its efficiency and safety in term neonates with icterus. This was done in a single blind and random fashion. The main inclusion criteria included gestational age less than 37, bilirubin level between 18 and 21.9 and those of the exclusion were hemolysis, age less than two and more than 14 and high level of direct bilirubin. The sample size included 182 uncomplicated neonates whom were randomly assigned into two different groups. The control and intervention groups were put under phototherapy without and with plastic cover, respectively. The neonates were checked for the appearance of probable complications such as hyperthermia, dehydration and so on, while receiving phototherapy. The main outcome of this study was to see the effect of the cover, put around the equipment, on the level of bilirubin.

Iran (Islamic Republic of)

Phone

00988314276303 2292 داخلی

Email address

homa_babaei@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2009-11-03, 1388/08/12

Expected recruitment end date

2010-10-27, 1389/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010184961N1**

Registration date: **2010-10-31, 1389/08/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-10-31, 1389/08/09

Registrant information

Name

Homa Babaei

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Scientific title

The efficacy and safety of white plastic cover around phototherapy unit in term jaundiced neonate: A randomized controlled trial

Public title

The efficacy and safety of white plastic cover around phototherapy unit in term jaundiced neonate: A randomized controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: neonates who had gestational age of 37 and were more than 2500g with the Bilirubin level between 18 and 21, at the beginning of the phototherapy
Exclusion criteria: congenital malformations, hemolysis, increased direct Bilirubin (>20% of the total Bilirubin), sepsis, age less than 48 hours and more than 2 weeks, at the beginning of phototherapy

Age

From **2 years** old to **14 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **182**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

Bulding no=2, Sepah Avenue, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

6714415333

Approval date

2009-11-03, 1388/08/12

Ethics committee reference number

33386

Health conditions studied

1

Description of health condition studied

Hyperbilirubin in neonate

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Serum Bilirubin level

Timepoint

Each 12 hours

Method of measurement

Laboratory Bilirubin Assay Kit

Secondary outcomes

1

Description

Body Temperature

Timepoint

each 6 hours

Method of measurement

Thermometer

2

Description

Dehydration

Timepoint

each 6 hours

Method of measurement

physical examination

3

Description

stool consistence

Timepoint

each 6 hours

Method of measurement

inspection

Intervention groups

1

Description

The intervention groups were put under single phototherapy with plastic cover

Category

Treatment - Devices

2

Description

The control group were put under single phototherapy without plastic cover.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Kermanshah University of Medical Sciences,

Full name of responsible person

Homa Babaei

Street address

Department of pediatrics, Imam Reza Hospital,
Kermanshah University of Medical Sciences

City

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Najafi

Street address

Deputy of Research, Kermanshah University of
Medical Sciences

City

Kermanshah

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

Yes

Title of funding source

Kermanshah 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**

Kermanshah University of Medical Sciences

Full name of responsible person

Homa Babaei, MD

Position

Neonatologist

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

Department of Pediatrics, Imam Reza Hospital,
Kermanshah

City

Kermanshah

Postal code

6714415333

Phone

+98 83 1427 6303

Fax

+98 83 1428 2670

Email

homa_babaei @kums.ac.irhoma_babaei @yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Homa Babaei, MD

Position

Neonatologist

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

Department of Pediatrics, Imam Reza Hospital,
Kermanshah

City

Kermanshah

Postal code

6714415333

Phone

+98 83 1427 6303

Fax**Email**

homa_babaei@kums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Homa Babaei

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Department of pediatrics, Imam Reza Hospital,
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Kermanshah

Postal code

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Phone

+98 83 1427 6303

Fax**Email**

homa_babaei@kums.ac.ir

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