

# 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)

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##### 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**

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**Fax****Email**

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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*