

# 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)

##### Phone

+98 34 1322 2250

##### Email address

bbbijari@kmu.ac.ir

##### 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**

Kerman

**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**

Zafar 2 Avenue, 4th west alley

**City**

Kerman

**Postal code****Phone**

+98 34 1322 2269

**Fax****Email**

bbbijari@yahoo.com

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

Kerman University of medical sciences

**Full name of responsible person**

Dr Bahareh Bahman Bijari

**Position**

Neonatal fellowship

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

Zafar 2 Av. 4th west alley

**City**

Kerman

**Postal code**

7618696815

**Phone**

+98 34 1322 2269

**Fax****Email**

bbbijari@yahoo.com

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

Kerman University of medical sciences

**Full name of responsible person**

Dr Pardis Sasani

**Position**

General practitioner

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

No.2, phase 1, Kooye sarjangaldari, Jomhoori Blvd

**City**

Kerman

**Postal code**

7618747316

**Phone**

+98 34 1211 3882

**Fax****Email**

pardis\_sasani@yahoo.com

**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*