

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Effect of Intravenous Fluid therapy on Serum level of Bilirubin in icteric neonates during phototherapy

#### Protocol summary

##### Summary

Through this randomized clinical trial, 100 neonates admitted with jaundice in neonates wards of Kashan hospitals in 2013, will be studied. Inclusion criteria included: gestational age > 38 weeks; age > 24 hours on admission; serum level of total bilirubin > 15 mg/dl; indirect hyperbilirubinemia. Exclusion criteria included: necessary to fluid therapy except icter; preterm and LBW neonates; hemolytic jaundice; sepsis; prolonged icter. Patients randomly assign into two groups (intervention or control). control group (N=50 cases) receiving only phototherapy but intervention group (N=50 cases) receiving intravenous fluid plus phototherapy. Intravenous fluids containing dextrose 10% equal amounts of maintenance with 30 mEq/L sodium and 20 mEq/L potassium. Total and indirect bilirubin levels will be measured in two groups at admission and 6, 12, 24 hours after treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013022711145N5**  
Registration date: **2013-03-26, 1392/01/06**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-03-26, 1392/01/06

##### Registrant information

###### Name

Mohammad Reza Sharif

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5554 0026

###### Email address

sharif\_m@kaums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Kashan University of Medical Sciences

###### Expected recruitment start date

2013-03-21, 1392/01/01

###### Expected recruitment end date

2014-03-21, 1393/01/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Effect of Intravenous Fluid therapy on Serum level of Bilirubin in icteric neonates during phototherapy

###### Public title

Effect of Intravenous Fluid therapy on Serum level of Bilirubin in icteric neonates during phototherapy

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: Gestational age > 38 weeks; age > 24 hours on admission; serum level of total bilirubin > 15 mg/dl; indirect hyperbilirubinemia Exclusion criteria: Necessary to fluid therapy except icter; preterm and LBW neonates; hemolytic jaundice; sepsis; prolonged icter

###### Age

From **1 year** old to **14 years** old

###### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **100**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## 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

Kashan University of Medical Sciences

##### Street address

5th Kilometer, Ghotbe Ravandi Bulv, Kashan

##### City

Kashan

##### Postal code

8715988141

#### Approval date

2013-03-12, 1391/12/22

#### Ethics committee reference number

4638/1/5/29/پ

## Health conditions studied

### 1

#### Description of health condition studied

Neonatal jaundice

#### ICD-10 code

P59.

#### ICD-10 code description

Neonatal jaundice due to unspecified causes

## Primary outcomes

### 1

#### Description

Serum bilirubin level

#### Timepoint

on admission, 6-12-24 hours later

#### Method of measurement

Blood test

## Secondary outcomes

### 1

#### Description

Duration of phototherapy

#### Timepoint

During hospitalization

#### Method of measurement

Calculating the hours of phototherapy

## Intervention groups

### 1

#### Description

Control: only phototherapy without intravenous fluid

#### Category

Treatment - Drugs

### 2

#### Description

Intervention: Intravenous fluids containing dextrose 10% equal amounts of maintenance with 30 mEq/L sodium and 20 mEq/L potassium plus phototherapy

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Beheshti Hospital

##### Full name of responsible person

Dr.Mohammad Reza Sharif

##### Street address

Beheshti Hospital, 5th Kilometer, Ghotbe Ravandi Bulv, Kashan

##### City

Kashan

### 2

#### Recruitment center

##### Name of recruitment center

Milad Hospital

##### Full name of responsible person

Dr.Mohammad Reza Sharif

##### Street address

Milad Hospital, Shahid Beheshti St, Kashan

##### City

Kashan

### 3

#### Recruitment center

##### Name of recruitment center

Shabih khani Hospital

##### Full name of responsible person

Dr.Mohammad Reza Sharif

**Street address**

Shabih khani Hospital, Shahid Beheshti St, Kashan

**City**

Kashan

mrsharifmd@yahoo.com

**Web page address**

www.drsharif.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr.Gholam Ali Hamidi

**Street address**

Kashan University of Medical Sciences, 5th Kilometer,  
Ghotbe Ravandi Bulv, Kashan

**City**

Kashan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kashan 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**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr.Mohammad Reza Sharif

**Position**

Associate Professor, Pediatric Infectious Diseases  
Subspecialist

**Other areas of specialty/work**

**Street address**

Kashan University of Medical Sciences, 5th Kilometer,  
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8715985131

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**Email**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate Professor, Pediatric Infectious Diseases  
Subspecialist

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## Person responsible for updating data

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## 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*