# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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: necessery 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)
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**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: Necessery 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

## 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
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**Position**
Associate Professor, Pediatric Infectious Diseases Subspecialist
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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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*