

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Effect of Intravenous Fluid therapy on decreasing serum bilirubin during intensive phototherapy in healthy term neonate with severe non hemolytic hyperbilirubinemia in comparison with phototherapy alone

Protocol summary

Summary

In this survey, the aim of study is comparing the effect of combined fluid therapy and phototherapy with the effect of phototherapy alone in treating the icteric neonates. Healthy term neonates with total bilirubin level more than 17 and less than 25 were included in our study. Neonates with any of these criteria were excluded from the study: prematurity, any systemic diseases or abnormalities, need to blood exchange, weight less than 2500 or more than 4000g and weight loss more than 3% in first ten days of life. This was a prospective clinical trial study. One hundred and sixty breast-fed neonates with hyperbilirubinemia who were admitted to neonatal ward of Besat Hospital (Hamedan, Iran) were divided randomly (alternately) into two groups of intervention and control. Eighty neonates received combination of 70cc/kg /day of 1/3²/3 serum (1/3N/S and 2/3D5W, Tehran-Darou serum Co., Tehran, Iran) and phototherapy (intervention group) and 80 neonates received phototherapy alone (control group). Mean serum bilirubin level was measured 6, 12, 24, 48, and 72 hours after the start of phototherapy and the duration of phototherapy was written in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012295497N1**
Registration date: **2013-01-12, 1391/10/23**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-12, 1391/10/23

Registrant information

Name

Abbas Moein

Name of organization / entity

Hamedan University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 81 1264 0050

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a.moein@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences and Health Services

Expected recruitment start date

2011-06-01, 1390/03/11

Expected recruitment end date

2012-06-01, 1391/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Intravenous Fluid therapy on decreasing serum bilirubin during intensive phototherapy in healthy term neonate with severe non hemolytic hyperbilirubinemia in comparison with phototherapy alone

Public title

Assessing the effect of serum therapy on decreasing of icterus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Term neonate (between 37 and 42 weeks of neonatal age). 2. All neonates between 2 and 28 days of old age. 3. $17 < \text{total serum bilirubin} < 25$. 4. $2500 \text{ g} < \text{weight} < 4000 \text{ g}$. 5. Without congenital anomaly and systemic diseases (sepsis, anemia, hemolysis, HMD).
Exclusion criteria: 1. Neonate < 37 weeks of old age. 2. Congenital anomaly, systemic disease (sepsis, HMD, pneumonia, anemia, hemolysis). 3. Demand to blood exchange. 4. $4000 \text{ g} < \text{Weight} < 2500 \text{ g}$. 5. Neonates who in first ten days of life loss more than 3% of weight.

Age

From **2 years** old to **28 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

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

Ethics committee of Hamedan University of Medical Sciences and Health Services

Street address

Opposite Mardom Park, Shahid Fahmide Ave, Mahdieh Ave, Hamedan

City

Hamedan

Postal code

Approval date

2011-05-14, 1390/02/24

Ethics committee reference number

2075/35/16/پ/د

Health conditions studied

1

Description of health condition studied

Neonatal jaundice

ICD-10 code

P59

ICD-10 code description

Neonatal jaundice from other and un specified causes

Primary outcomes

1

Description

Indirect bilirubin

Timepoint

During at 6, 12, 24, 48 and 72 hours after beginning of phototherapy

Method of measurement

Measuring serum bilirubin(diazo method)

Secondary outcomes

1

Description

Age

Timepoint

Between 2 and 28 days of old age

Method of measurement

Since birthday

2

Description

Duration of hospitalization

Timepoint

6- 12- 24- 48 and 72 hours after phototherapy

Method of measurement

Hours

3

Description

Sex

Timepoint

Beginning of study

Method of measurement

Physical examination

4

Description

Blood group

Timepoint

Beginning of study

Method of measurement

Laboratory test

Intervention groups

1

Description

One hundred sixty neonates with hyperbilirubinemia who were admitted at neonate ward of Besat hospital of Hamedan, Iran and who are breast feeding were divided to two groups. Eighty neonates in intervention group receive 70 cc per kg of $\frac{1}{3}$ - $\frac{2}{3}$ serum daily with phototherapy (together) . The serum that was used, contains sodium as $\frac{1}{3}$ of normal saline and glucose as of $\frac{2}{3}$ dextrose 5% and use this serum intravenous until total bilirubin being less than 17. This serum made in Tehran Darou Company.

Category

Treatment - Other

2

Description

One hundred sixty neonates with hyperbilirubinemia who were admitted at neonate ward of Besat hospital of Hamedan, Iran and who are breast feeding were divided to two groups. Eighty neonates (control) receive only phototherapy alone.

Category

Early detection

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Abbas Moein

Street address

Hamedan Besat Hospital

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamedan University of Medical Sciences and Health Services

Full name of responsible person

Dr Mohammad Alikhani

Street address

Opposite Mardom Park, Shahid Fahmide Ave, Mahdieh Ave, Hamedan

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Hamedan University of Medical Sciences and Health Services

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

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moein

Position

Resident

Other areas of specialty/work

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Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moein

Position

Resident

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

Besat Hospital

City

Hamedan

Postal code**Phone****Fax****Email****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