

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Intravenous Immunoglobulin on Jaundice Induced by Neonatal Isoimmune Hemolytic Disease

Protocol summary

Study aim

To evaluate the effects of IVIG in the control of jaundice caused by neonatal hemolytic disease in Motahari Hospital of Urmia

Design

A double-blind randomized clinical trial with a control group, sample of 76 neonates in three equal groups

Settings and conduct

In this double blind randomized clinical trial study, neonates with jaundice in neonatal ward of Motahari hospital of Urmia were divided into three groups. Random allocation was done using randomizer website. Length of stay, duration of phototherapy, need for Plasmapheresis, bilirubin and hemoglobin were evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent of parents, Neonates with Jaundice. Exclusion criteria: Neonates weighing less than 2500 grams

Intervention groups

The first group (prophylaxis group with IVIG 0.5 g / kg within 4 hours), the second group (treatment group with IVIG 0.5 g / kg within 12 hours) and the third group (control group)

Main outcome variables

Length of stay, duration of phototherapy, need for Plasmapheresis, bilirubin, hemoglobin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171218037936N3**

Registration date: **2020-03-07, 1398/12/17**

Registration timing: **retrospective**

Last update: **2020-03-07, 1398/12/17**

Update count: **0**

Registration date

2020-03-07, 1398/12/17

Registrant information

Name

Kamran Dehghan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3365 4154

Email address

dehghan.k@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-22, 1398/01/02

Expected recruitment end date

2019-09-04, 1398/06/13

Actual recruitment start date

2019-05-01, 1398/02/11

Actual recruitment end date

2019-10-24, 1398/08/02

Trial completion date

2019-10-24, 1398/08/02

Scientific title

The Effect of Intravenous Immunoglobulin on Jaundice Induced by Neonatal Isoimmune Hemolytic Disease

Public title

The Effect of Intravenous Immunoglobulin on Jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Neonates with Jaundice Informed consent of parents

Exclusion criteria:

Neonates weighing less than 2500 grams

Age
From **1 day** old to **30 days** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **76**
Actual sample size reached: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, all eligible patients were assigned to three groups using random sequence extraction from the computer (via www.randomization.com) and simple randomization. The resulting random numbers, i.e. the allocation of patients to groups, was concealed using sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, clinical care giver and statistical analyzer were not aware of groups assigned to neonates.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Urmia University of Medical Sciences

Street address
Urmia, Resalat Boulevard, Emergency alley

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2019-04-16, 1398/01/27

Ethics committee reference number
IR.USMU.REC.1398.030

Health conditions studied

1

Description of health condition studied

Jaundice of neonates

ICD-10 code

P58.8

ICD-10 code description

Neonatal jaundice due to other specified excessive hemolysis

Primary outcomes

1

Description

Duration of hospitalization

Timepoint

Once on the time of discharge

Method of measurement

The length of time that the neonate is hospitalized

2

Description

Duration of phototherapy

Timepoint

Once on the time of discharge

Method of measurement

Using a phototherapy machine

3

Description

Plasmapheresis

Timepoint

Once on the time of discharge

Method of measurement

Based on file information

4

Description

Bilirubin

Timepoint

Measured 4 times every 12 hours

Method of measurement

Blood sampling

5

Description

Hemoglobin

Timepoint

Measured 4 times every 12 hours

Method of measurement

Blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The first group (prophylaxis group) included the neonates who received IVIG at dose of 0.5 g / kg within 4 hours. IVIG used in the study had the trade name of Intratect manufactured by Biotest Company of Germany with 5% (50 g/l) solutions, each containing 50 mg immunoglobulin.

Category

Treatment - Drugs

2

Description

Intervention group 2: The second group (treatment group) included the neonates who received 0.5 g/kg of IVIG in the case of uncontrolled and progress of jaundice (hemodialysis) characterized by an increase in bilirubin number despite phototherapy and a decrease in hemoglobin, based on the Bhutani nomogram as approached the blood transfusion number (within the range of 3 gr / dl).

Category

Treatment - Drugs

3

Description

Control group: The third group (control group) included the neonates who received standard phototherapy (Intensive phototherapy). In case of lack of control of jaundice progression in the first and second groups, the second dose of IVIG was injected at the same dose of 0.5 g / kg 12 hours after the previous dose.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Hospital

Full name of responsible person

Kamran Dehghan

Street address

Urmia, Resalat Boulevard, Emergency alley

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dehghan.k@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr Iraj Mohebbi

Street address

Urmia University of Medical Sciences-Resalat Blvd-
Emergency Alley. Urmia West Azarbaijan Iran, Islamic
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Email

mohebbi_iraj@yahoo.co.uk

Web page address

<http://faculty.umsu.ac.ir/Site/CV.aspx?STID=15&Ln=f>
a

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Kamran Dehghan

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Any information without the need for patients' names will be available

When the data will become available and for how long

Six months after publication

To whom data/document is available

Faculty members

Under which criteria data/document could be used

Email to Dr. Kamran Dehghan

From where data/document is obtainable

Just email to Dr. Kamran Dehghan

What processes are involved for a request to access data/document

Just email to Dr. Kamran Dehghan

Comments