Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the Effect of Ursodeoxycholic Acid on total bilirubin of neonate with neonatal indirect hyperbilirubinemia who have Glucose-6-phosphate dehydrogenase deficiency compare to control group

Protocol summary

Study aim
The effect of Ursodioxycholic acide (UDCA) on indirect bilirubin reduction in neonatal hyperbilirubinemia has been shown in a few studies, therefore, we aimed to investigate the effect of this drug in neonates with Glucose 6 phosphate dehydrogenase deficiency (G6pd) which can induce severe indirect hyperbilirubinemia.

Design
This is a clinical trial study phase 3 in neonates with G6PD deficiency and hyperbilirubinemia which performs in two parallel groups receiving drug and placebo. The study is a triple blind, block randomized design. The sample size is calculated to be 50.

Settings and conduct
The study is carried out on neonates with neonatal jaundice who are G6PD deficient and are admitted to Zeinabiye and Hafiz Hospitals in Shiraz for phototherapy. The nurse who is responsible for providing the medication, the carers, the doctors, and the bilirubin test laboratory and the data analyzer are not aware of intervention type.

Participants/Inclusion and exclusion criteria
This study will be performed on neonates with G6PD who are admitted with the diagnosis of hyperbilirubinemia for phototherapy. Inclusion criteria: G6pd deficiency, exclusive breastfeeding, over one day old, total bilirubin above 14 mg / dL and below 20 mg / dL and direct bilirubin below 2 mg / dL Exclusion criteria: Blood maladaptation, cholestatic or hepatic disease or infection and septicemia or diabetic mother infant.

Intervention groups
The intervention group will receive oral drug of Ursodioxycholic acide10 mg/kg (2cc syrup/kg) daily divided into 2 doses every 12 hours. Dr. Obidi's 300 mg capsule is used for the preparation of the syrups of 300 mg in 60 ml water. At the same time intervals, the control group received the same volume placebo syrup. Both groups receive standard phototherapy.

Main outcome variables
Total bilirubin; median admission time; drug adverse effects (Nausea, vomiting, rash)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190604043813N2**
Registration date: **2020-03-31, 1399/01/12**
Registration timing: **prospective**

Last update: **2020-03-31, 1399/01/12**
Update count: **0**

Registration date
2020-03-31, 1399/01/12

Registrant information

Name
Hourvash Akbari Haghighinejad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Effect of Ursodeoxycholic Acid on total bilirubin of neonate with neonatal indirect hyperbilirubinemia who have Glucose-6-phosphate dehydrogenase deficiency compare to control group

Public title

The effect of Ursodeoxycholic Acid on neonatal jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Exclusive breastfeeding, Total bilirubin levels above 14 mg / dL and below 20 mg / dL, Direct bilirubin levels below 2 mg / dL. Age above 1 day Glucose 6 phosphate dehydrogenase deficiency Parent consent

Exclusion criteria:

Infection and septicemia Uunderlying disease such as heart and liver disease The diabetic mother Rh incompatibility

Age

From **1 day** old to **10 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **3**

-

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization list with block size of 4 generates by https://www.sealedenvelope.com/simple-randomiser/v1/lists.The sample size , size of blocks and study groups are given to the system, and the system determines the order of the blocks and the order in each block in a list. The drug and placebo are arranged in a box according to the list by a pharmacist and are given to one of the nurses responsible for the research to be given to the infants.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drug and placebo which are prepared in syrup and are distinguishable by A and B labels will be arrange in a box according to the randomization list by the pharmacist who has no responsibility for patients care . The box will be given to a nurse who is unaware of the intervention type and she give the treatment in specified order . Caregivers, physicians, and the lab conducting the bilirubin test are not aware of the treatment. The results are compiled and analyzed by a statistician who is not aware of the intervention type.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of research of Shiraz Medical School

Street address

Family medicine department , Namazi Hospital, Zand street

City

Shiraz

Province

Fars

Postal code

7184983858

Approval date

2017-11-22, 1396/09/01

Ethics committee reference number

IR.SUMS.MED.REC.1396.94

Health conditions studied

1

Description of health condition studied

Neonatal indirect hyperbilirubinemia

ICD-10 code

P59.8

ICD-10 code description

Neonatal jaundice from other specified causes

Primary outcomes

1

Description

Total bilirubin

Timepoint

Every 24 hours until total bilirubin fall bellow 10 mg/dl

Method of measurement

Total bilirubin is measured by the diazo method.

Secondary outcomes

1

Description
Median admission time
Timepoint
Once
Method of measurement
The number of hospitalization days

Intervention groups

1

Description
Intervention group: The intervention group will receive oral drug of Ursodeoxycholic acid (UDCA) 10 mg/kg (2cc/kg) daily divided into 2 doses every 12 hours. Dr. Obidi's 300 mg capsule is used for the preparation of the syrups of 300 mg in 60 ml water. Both intervention and control groups receive standard phototherapy and the baby's eye and genitalia are covered. The drug is continued until the bilirubin level is below 10 mg /dl.
Category
Treatment - Drugs

2

Description
Control group: At 12 hours intervals, the control group received the same volume placebo syrup (1cc/kg). Both groups receive standard phototherapy and the baby's eye and genitalia are covered. The placebo is continued until the bilirubin level is below 10 mg /dl.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Zeinabiye Hospital
Full name of responsible person
Mehrdad Rezaie
Street address
Sibuye Blvd.
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2

Recruitment center
Name of recruitment center
Hafez Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Hourvash Akbari Haghighinejad
Position
Assistant Professor
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Person responsible for updating data

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Fax
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hhaghighi@sums.ac.ir

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
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data without name, protocol, and study report can be shared
When the data will become available and for how long
6 months after publication
To whom data/document is available
all people who request to access the documents
Under which criteria data/document could be used
With reference to the original study , data will be available for systematic review and meta-analysis.
From where data/document is obtainable
hhaghighi@sums.ac.ir
What processes are involved for a request to access data/document
request send via email mentioned above
Comments