Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of ursodeoxycholic acid in reducing hospitalization for intensive phototherapy in neonates with indirect hyperbilirubinemia referred to outpatient clinics in comparison with the control group

Protocol summary

Study aim

Investigate the effect of Ursodioxycholic acid (UDCA) in reducing hospital admission rate for intensive phototherapy in neonate with indirect hyperbilirubinemia

Design

This is a clinical trial study phase 3 in neonates with 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 148.

Settings and conduct

The study is performed on neonate with jaundice who are brought to Imam Reza , Hazrat Zeinab or Hafez outpatient clinics in Shiraz. Caregivers, physicians, and data analysts are not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Neonates with a bilirubin between 3 mg / dL less than required for intensive phototherapy and the level required for intensive phototherapy in hospital participate in this study. All of these neonates need phototherapy at home. Other inclusion criteria: neonate with gestational age 35 weeks or more, exclusive breastfeeding, age over one day and direct bilirubin below 2 mg / dL . Exclusion criteria: Blood incompatibility, cardiac or liver disease , infection and sepsis or infant of diabetic mother

Intervention groups

Ursodioxycholic acid suspension (prepared from 300 mg capsule of Alborz Darou Pharmaceutical Co. as a suspension of 60 mg / 1cc) prescribe orally as 10 mg /kg body weight of the neonate, divided into 2 doses every 12 hours . At the same intervals, the control group is given the same volume of placebo. Both groups receive medication or placebo until their bilirubin drops below 3 units less than intensive phototherapy level.

Main outcome variables

Hospitalization rate for intensive phototherapy; Total bilirubin; Medication side effects (nausea, vomiting, skin rash)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190604043813N4**
Registration date: **2021-06-21, 1400/03/31**
Registration timing: **prospective**

Last update: **2021-06-21, 1400/03/31**
Update count: **0**

Registration date

2021-06-21, 1400/03/31

Registrant information

Name

Hourvash Akbari Haghighinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4967

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of ursodeoxycholic acid in reducing hospitalization for intensive phototherapy in neonates with indirect hyperbilirubinemia referred to outpatient clinics in comparison with the control group

Public title

Effect of ursodeoxycholic acid in reducing hospitalization for phototherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Exclusive breastfeeding, Age above 1 day Neonate born with gestational age 35 weeks or more Total bilirubin between 3 mg / dL less than the level required for intensive phototherapy treatment in the hospital and the level required for hospitalization Direct bilirubin levels below 2 mg / dL. Parent consent Infants whose parents agree not to use herbal or traditional medicines during the study period.

Exclusion criteria:

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

Age

From **2 days** old to **15 days** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **148**

More than 1 sample in each individual

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

Total bilirubin

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 a doctor who is responsible for the research to be given to the neonates.

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 doctor who is unaware of the intervention type and he give the treatment in specified order . Caregivers, physicians 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

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7184983858

Approval date

2021-05-03, 1400/02/13

Ethics committee reference number

IR.SUMS.MED.REC.1400.076

Health conditions studied

1

Description of health condition studied

Neonatal indirect hyperbilirubinemia

ICD-10 code

P59

ICD-10 code description

Neonatal jaundice from other and unspecified causes

Primary outcomes

1

Description

Hospitalization rate

Timepoint

Weekly, from week 1 to 4 after the start of the intervention

Method of measurement

Asking the parents about admission in hospital for

phototherapy

Secondary outcomes

1

Description
Total bilirubin
Timepoint
Every 24 hours until the bilirubin reaches 3 mg / dl below the level required for intensive phototherapy
Method of measurement
Capillary method and diazo laboratory method

2

Description
Adverse effect of drug
Timepoint
Till 4 weeks after the start of the drug
Method of measurement
Asking the parents about adverse effect

Intervention groups

1

Description
Intervention group:The intervention group will receive oral drug of Ursodeoxycholic acid (UDCA) 10 mg/kg (1/6cc/kg) daily divided into 2 doses every 12 hours. UDCA 300 mg capsule(provided by Alborz Darou Company, Tehran, Iran) is used for the preparation of 60 mg/1cc suspension. Both intervention and control groups receive standard phototherapy at home and the baby's eye and genitalia are covered. The drug is continued until the bilirubin level is below 3mg /dl lower than the level require for intensive phototherapy.
Category
Treatment - Drugs

2

Description
Control group: At 12 hours intervals, the control group received the same volume placebo suspension (1/6cc/kg). Both intervention and control groups receive standard phototherapy at home and the baby's eye and genitalia are covered. The drug is continued until the bilirubin level is below 3mg /dl lower than the level require for intensive phototherapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza clinic
Full name of responsible person
Mehrdad Rezaie
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2

Recruitment center
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3

Recruitment center
Name of recruitment center
Clinic of Zeinabiye Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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vcrdep@sums.ac.ir

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

Latest degree
Specialist

Other areas of specialty/work
Family Physician

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Person responsible for scientific inquiries

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Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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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
Not applicable
Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After the publication of the main article, all collected de-identified IPD can be shared.
When the data will become available and for how long
From the time of publication until 6 months later
To whom data/document is available
All people who request to access the documents
Under which criteria data/document could be used
After the publication of the main article, if the source of the main study is mentioned, the 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
The request can be sent to the email adress mentioned above
Comments