Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of adding oral ursodeoxycholic acid to phototherapy and phototherapy alone on indirect hyperbilirubinemia in term infants with G6PDd and ABO and Rh incompatibility - a randomized controlled clinical trial study

Protocol summary

Study aim
Determining and comparing the effect of oral ursodeoxycholic acid along with phototherapy and phototherapy alone on indirect hyperbilirubinemia in 3- to 10-day-old term infants with G6PDd and ABO and Rh incompatibility

Design
This research is a single-blind randomized clinical trial study with a control group of term infants with the mentioned risk factors who receive phototherapy only, randomization before starting the program using https://www.sealedenvelope.com software, taking into account 53 people in each 2 groups (Urso group, photo and phototherapy alone) will be done in blocks of 4

Settings and conduct
This research is a clinical trial study that will be conducted in 17 Shahrivar hospital in Rasht on 3-10 day term infants with risk factors

Participants/Inclusion and exclusion criteria
Inclusion criteria: infants aged 3 to 10 days, birth weight: 2500 to 4000 grams, exclusive breastfeeding, gestational age: 37 to 41 weeks, total bilirubin 14 to 20 and direct is less than 1 mg/dl. Exclusion criteria:history of any neurological disease, children with a history of seizures, electrolyte imbalance related to chronic disease (measured by blood test), direct hyperbilirubinemia (measured by blood test), septicemia, diseases leading to hyperbilirubinemia (Crigler-Najjar syndrome, Gilbert syndrome, hyperthyroid, hypothyroid, liver diseases), babies with jaundice w/o ABO and Rh incompatibility and G6PDD,receiving IVIG,preterm infants and babies of diabetic mothers,obstruction of the bile ducts and babies who have 2 or more risk factors at once.

Intervention groups
3- to 10-day-old term infants with indirect hyperbilirubinemia with G6PDd and ABO and Rh incompatibility who receive ursodeoxycholic acid at a dose of 10 mg per kilogram per day in two equal doses and phototherapy and the control group that receives phototherapy alone

Main outcome variables
Bilirubin level؛ duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130313012803N3**
Registration date: **2023-12-02, 1402/09/11**
Registration timing: **prospective**

Last update: **2023-12-02, 1402/09/11**
Update count: **0**

Registration date
2023-12-02, 1402/09/11

Registrant information

Name
Sadroddin Mahdipour

Name of organization / entity
Babol University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-06, 1402/09/15
Expected recruitment end date
2024-04-18, 1403/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of adding oral ursodeoxycholic acid to phototherapy and phototherapy alone on indirect hyperbilirubinemia in term infants with G6PDd and ABO and Rh incompatibility - a randomized controlled clinical trial study

Public title
Investigation of the effect of oral ursodeoxycholic acid drug in neonatal jaundice
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
parents' complete satisfaction with the presence of infants in the study infants aged 3 to 10 days birth weight: 2500 to 4000 grams exclusive breastfeeding gestational age: 37 to 41 weeks total bilirubin 14 to 20 and direct is less than 1 mg/dl
Exclusion criteria:
history of any neurological disease children with a history of seizures electrolyte imbalance related to chronic disease (measured by blood test), direct hyperbilirubinemia (measured by blood test) septicemia, diseases leading to hyperbilirubinemia (Crigler-Najjar syndrome, Gilbert syndrome, hyperthyroid, hypothyroid, liver diseases) babies with jaundice without ABO and Rh incompatibility and G6PDD receiving IVIG preterm infants babies of diabetic mothers obstruction of the bile ducts babies who have 2 or more of the mentioned risk factors at once
Age
From **3 days** old to **10 days** old
Gender
Both

Phase
4
Groups that have been masked

- Participant

Sample size
Target sample size: **106**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done before the start of the program using the https://www.sealedenvelope.com software, considering 53 people in each 2 groups (Urso group, photo and phototherapy alone) in blocks of 4, and each of them are placed in a separate envelope according to the list obtained from the software and the envelope will be sealed and will be given to a third party. If the patient comes and is eligible, the envelope will be opened and according to the desired sequence, without knowing the next treatment, the patient is treated.
Blinding (investigator's opinion)
Single blinded
Blinding description
The method of allocating children in two groups is based on quadruple random blocks. If the children meet the entry criteria, they will be placed in two groups A (Urso) and B (control). Before starting the study, this list is kept hidden in the children's research center in a sealed envelope. After starting the reading list, the children will be placed in two groups, A and B, that is, Ursu and control. Random allocation will be done by a third person who is unaware of the study and the groups, and the researchers will not be involved in this matter.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Vice-Chancellor of Gilan University of Medical SciencesIR
Street address
Siadati St
City
Rasht
Province
Guilan
Postal code
4456678709
Approval date
2023-10-18, 1402/07/26
Ethics committee reference number
IR.GUMS.REC.1402.372

Health conditions studied

1

Description of health condition studied
Infant hyperbilirubinemia
ICD-10 code
E80
ICD-10 code description
Disorders of porphyrin and bilirubin metabolism

Primary outcomes

1

Description
Bilirubin level
Timepoint
The studied infants are checked for hyperbilirubinemia upon arrival and then at least once every 12-24 hours with a serum sample
Method of measurement
BT3500 device and photometric method using 2 and 4 dichloroaniline (DCA)

Secondary outcomes

1

Description
Duration of hospitalization
Timepoint
During the period of hospitalization of the infant, the pediatric resident visits her every 8 hours and examines her for possible complications
Method of measurement
Examination by the pediatric resident

2

Description
Drug side effects
Timepoint
During the period of hospitalization of the infant, the pediatric resident visits her every 8 hours and examines her for possible complications
Method of measurement
Examination by the pediatric resident

Intervention groups

1

Description
Intervention group: 3 to 10-day term infants with indirect hyperbilirubinemia with G6PDd and ABO and Rh incompatibility who receive ursodeoxycholic acid at a dose of 10 mg per kilogram per day in two equal doses along with phototherapy
Category
Treatment - Drugs

2

Description
Control group: 3 to 10-day term infants with indirect hyperbilirubinemia with G6PDd and ABO and Rh incompatibility receiving phototherapy alone
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
17 Shahrivar Hospital, Rasht
Full name of responsible person
Dr. Sadruddin Mehdipour
Street address
Siadati St
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4456678709
Phone
+98 13 3336 9002
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Smb1355@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr. Ramyar Farzan
Street address
Guilan University of Medical Sciences, Gas Square
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Rasht
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Guilan
Postal code
4144444444
Phone
+98 13 3333 5820
Email
Research@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Dr. Sadruddin Mehdipour

Position
Neonatologist

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Due to ethical issues

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available