

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Therapeutic effect of oral ursodeoxycholic acid on indirect hyperbilirubinemia in full-term neonates undergoing phototherapy in hospital 17 Shahrivar - a randomized controlled clinical trial

Protocol summary

Study aim

Comparison of oral Urso with phototherapy and phototherapy alone in indirect hyperbilirubinemia reduction in term neonates undergoing phototherapy in hospital 17 Shahrivar

Design

A clinical trial with the control group, without blinding, randomized, phase 3, on 106 patients. sealed envelope software is used for randomization.

Settings and conduct

This study is a randomized clinical trial that will be performed on 3 to 7-day old neonates who are admitted due to jaundice after receiving the code of ethics for 8 months in 17 Shahrivar Hospital in Rasht. After selecting the infants according to the inclusion and exclusion criteria, written consent will be obtained from the parents and in the next step. Patients will be divided into 2 groups. Group A will receive oral Urso with phototherapy and group B will receive phototherapy alone (control). The drug is evaluated and visited by a Pediatric resident, and in case of complications, the drug will be discontinued. 1- Urso is administered orally at a dose of 10 mg/kg in divided doses every 12 hours and at the time of hospitalization. This dose will be dissolved in breast milk.

Participants/Inclusion and exclusion criteria

Inclusion criteria include the complete satisfaction of parents with the presence of children in the study, birth weight: 2500 to 4000 grams, exclusive breastfeeding, gestational age 38 to 41 weeks, age 3 to 7 days, total bilirubin 14 to 20 and less direct Of 2. Criteria for non-entry include ABO and RH incompatibility, G6PDd, direct hyperbilirubinemia, septicemia

Intervention groups

Urso at a dose of 10 mg/kg daily in infants receiving phototherapy during hospitalization

Main outcome variables

The primary outcome is bilirubin levels, which will be recorded within three to four days of hospitalization. The secondary outcome is the length of hospital stay - drug side effects and the timing of bilirubin testing.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210201050199N1**

Registration date: **2021-04-03, 1400/01/14**

Registration timing: **prospective**

Last update: **2021-04-03, 1400/01/14**

Update count: **0**

Registration date

2021-04-03, 1400/01/14

Registrant information

Name

manijeh Tabrizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9002

Email address

drs.tabrizi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-19, 1400/01/30

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Therapeutic effect of oral ursodeoxycholic acid on indirect hyperbilirubinemia in full-term neonates undergoing phototherapy in hospital 17 Shahrivar - a randomized controlled clinical trial

Public title
Therapeutic effect of oral ursodeoxycholic acid on indirect hyperbilirubinemia in full-term neonates undergoing phototherapy in hospital 17 Shahrivar - a randomized controlled clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Parents' complete satisfaction with the presence of children in the study Birth weight 2500 to 4000 grams Exclusive breastfeeding, Gestational age 38 to 41 weeks Age 3 to 7 days Total bilirubin 14 to 20 and direct bilirubin less than 2
Exclusion criteria:
ABO and RH incompatibility G6PD enzyme deficiency Direct hyperbilirubinemia Septicemia Diseases leading to hyperbilirubinemia (carpenter Kriegler syndrome, Gilbert syndrome, hyperthyroidism, hypothyroidism, liver disease) Preterm Neonate of mothers with gestational diabetes mellitus

Age
From **3 days** old to **7 days** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization before the start of the program will be done by the software <https://www.sealedenvelope.com> with 53 people in each of the 2 groups (Urso and Photo and Control groups) in blocks of 4 and each of them inside A separate envelope is placed according to the list obtained from the software and is closed in it and will be given to the third person. If the patient visits and is eligible, the envelope is opened and treated according to the desired sequence without knowing the next treatment. . It should be noted that according to the grouping performed, patients will be divided into 2 groups based on random assignment done with the software. It is the responsibility of the pediatric resident to evaluate other variables and variables related to hyperbilirubinemia and to evaluate the side effects of the drug on a daily basis during hospitalization. Group A will

receive oral Urso with phototherapy and group B will receive phototherapy alone (control). • 1, 4, 1, Group B • 1, 4, 2, Group B • 1, 4, 3, Group A • 1, 4, 4, Group A • 2, 4, 1, Group B

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 the vice chancellor of Guilan University of Medical Sciences

Street address

Siadati

City

rasht

Province

Guilan

Postal code

4144444444

Approval date

2021-03-03, 1399/12/13

Ethics committee reference number

IR.GUMS.REC.1399.645

Health conditions studied

1

Description of health condition studied

Hyperbilirubinemia

ICD-10 code

E80.6

ICD-10 code description

Other disorders of bilirubin metabolism

Primary outcomes

1

Description

Total bilirubin

Timepoint

Every 24 hours

Method of measurement

Autoanalyzer device

Secondary outcomes

1

Description

Indirect bilirubin

Timepoint

Every 24 hours

Method of measurement

Autoanalyzer device

Intervention groups

1

Description

Intervention group: those who will receive oral Urso with phototherapy (administering Urso orally at a dose of 10 mg/kg in divided doses every 12 hours and at the time of hospitalization dissolved in breast milk)

Category

Treatment - Drugs

2

Description

Control group: those who will receive phototherapy alone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

17 Shahrivar Children's Hospital

Full name of responsible person

Manijeh Tabrizi

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

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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

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

Manijeh Tabrizi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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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

Regarding the ethical issues and confidentiality

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