

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Evaluating the therapeutic effect of ursodeoxycholic acid on the reduction of serum bilirubin in neonates with prolonged jaundice: A randomized controlled clinical trial study

#### Protocol summary

##### Study aim

The aim of this study is to investigate the therapeutic effects of ursodeoxycholic acid on the reduction of serum bilirubin in a different target group, i.e. infants with prolonged jaundice who are hospitalized and not undergoing phototherapy.

##### Design

A paralleled controlled randomized clinical trial, without blinding, phase 3 on 58 patients. Four random blocks method is used for randomization.

##### Settings and conduct

A randomized clinical trial will be done at 17 Shahrivar Hospital, Rasht, after obtaining informed consent from parents. It is a non-blinded study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Serum bilirubin above 10 mg/dl3  
Indirect hyperbilirubinemia (below 1)  
Exclusion criteria:  
Conjugated hyperbilirubinemia (direct bilirubin above 1)  
Disruption of TSH and T4  
Clinical evidence of infection  
Urinary tract infection  
Sick neonates

##### Intervention groups

Intervention group: Administration of ursodeoxycholic acid capsules with a dose of 10 mg per kilogram of baby's weight daily in two divided doses to the intervention group for 5 days dissolved in cooled boiled water. Control group: No medication is prescribed to the control group and they receive the recommended expectant treatment and monitoring.

##### Main outcome variables

Total and direct serum bilirubin on the day of the visit and 5 days after the intervention and drug administration and checking the reduction of bilirubin and comparing the numbers in 2 groups

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180228038895N2**  
Registration date: **2023-06-24, 1402/04/03**  
Registration timing: **registered\_while\_recruiting**

Last update: **2023-06-24, 1402/04/03**

Update count: **0**

##### Registration date

2023-06-24, 1402/04/03

##### Registrant information

##### Name

Seyedeh Azadeh Hosseini Nouri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3336 9026

##### Email address

dr.azadehoseini@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-31, 1402/03/10

##### Expected recruitment end date

2024-02-29, 1402/12/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the therapeutic effect of ursodeoxycholic acid

on the reduction of serum bilirubin in neonates with prolonged jaundice: A randomized controlled clinical trial study

#### Public title

Evaluating the therapeutic effect of ursodeoxycholic acid on the reduction of serum bilirubin in neonates with prolonged jaundice

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Serum bilirubin above 10 mg/dl Indirect hyperbilirubinemia (below 1)

##### Exclusion criteria:

Conjugated hyperbilirubinemia (direct bilirubin above 1)  
Disruption of TSH and T4  
Clinical evidence of infection  
Urinary tract infection  
Sick neonates

#### Age

From **14 days** old to **28 days** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **58**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The randomization process will be carried out under the supervision of the project manager and by her and with the direct supervision of the statistician and the supervisor. Children with admission criteria based on daily visits to the children's clinic are included in the study through consecutive sampling. For randomization, the quadruple random block method is used. According to the sample size of 58 and equal to 29 people in each group, 16 blocks of 4 complete blocks and one double block will be selected. The random allocation of samples is based on the sequence list that is done through the random block allocation software. Children who meet the entry criteria are randomly assigned to Group A (ursodeoxycholic acid) and Group B (control) based on the list.

#### 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 Guilan University Of Medical Sciences

###### Street address

Siadati Ave, Namjoo Blvd

###### City

Rasht

###### Province

Guilan

###### Postal code

441774349

##### Approval date

2023-05-31, 1402/03/10

##### Ethics committee reference number

IR.GUMS.REC.1402.110

### Health conditions studied

#### 1

##### Description of health condition studied

Neonatal jaundice

##### ICD-10 code

P59

##### ICD-10 code description

Neonatal jaundice from other and unspecified causes

### Primary outcomes

#### 1

##### Description

Total and direct serum bilirubin

##### Timepoint

On the day of visit and 5 days after the intervention

##### Method of measurement

Measurement of serum bilirubin level in serum sample in laboratory with kit

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Administration of ursodeoxycholic acid capsules with a dose of 10 mg per kilogram of baby's weight daily in two divided doses to the intervention group for 5 days dissolved in cooled boiled water.

##### Category

Treatment - Drugs

#### 2

##### Description

Control group: No medication is prescribed to the control group and they receive the recommended expectant treatment and monitoring.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

17 Shahrivar Hospital.

**Full name of responsible person**

Seyedeh Azadeh Hosseini Nouri

**Street address**

Siadati Alley, Namjoo St, Gaz Square

**City**

Rasht

**Province**

Guilan

**Postal code**

4167811969

**Phone**

+98 13 3336 9026

**Email**

dr.azadehoseini@gums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Mohammadreza Naghipour

**Street address**

Siadati

**City**

Rasht

**Province**

Guilan

**Postal code**

4167811968

**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**

Seyedeh Azadeh Hosseini Nouri

**Position**

Proffessor

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

17shahrivar hospital, Siadati ave., Namjoo street, Gaz square

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**Email**

Dr.azadehoseini@gums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

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Proffessor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Seyedeh Azadeh Hosseini Nouri

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

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Dr.azadehoseini@gums.ac.ir

## 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 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