

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 2026

### Design, production, and comparison of serum level of Ursodeoxycholic acid Nanoemulsion with its capsule form in infants under 5 years with cholestasis

#### Protocol summary

##### Study aim

Design, production and comparison of serum level of Ursodeoxycholic acid nano emulsion with its capsule form in infants under 5 years of age with Cholestasis.

##### Design

This study will be performed on 100 infants, infants and children under 5 years of age with non-obstructive cholestasis admitted to Mofid and Mahdiah Children's Hospital in Tehran as a block randomized clinical trial divided into two equal groups. Patients after obtaining a history and clinical examination by a gastroenterologist or consultations performed in the neonatal ward of Mofid Children's Hospital and Mahdiah Hospital in Tehran and after confirmation of cholestasis and rejection of obstructive causes of cholestasis in a randomized clinical trial, (6 Blocks) are divided into two equal groups.

Patients are entered into the study by a checklist.

##### Settings and conduct

Mofid and Mahdiah Children's Hospital in Tehran.

##### Participants/Inclusion and exclusion criteria

This study will be performed on 100 infants, and children under 5 years of age with non-obstructive cholestasis admitted to Mofid and Mahdiah Children's Hospital in Tehran as a Blocked randomized clinical trial divided into two equal groups. Patients older than 5 years and patients with obstructive cholestasis before surgery are excluded from study.

##### Intervention groups

In group A, the drug will be in the form of Ursodeoxycholic acid nano emulsion in the form of drops with a dose of 15 mg/kg/d in three divided doses and in group B, the drug will be in the form of Ursodeoxycholic acid granules without capsules shell at the same dose of 15 mg/kg/ day.

##### Main outcome variables

Serum concentration of Ursodeoxycholic acid

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210306050598N1**

Registration date: **2021-05-14, 1400/02/24**

Registration timing: **prospective**

Last update: **2021-05-14, 1400/02/24**

Update count: **0**

##### Registration date

2021-05-14, 1400/02/24

##### Registrant information

##### Name

Peyman Ghasemi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4444 2690

##### Email address

peyman.ghasemi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-05, 1400/03/15

##### Expected recruitment end date

2022-02-24, 1400/12/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Design, production, and comparison of serum level of Ursodeoxycholic acid Nanoemulsion with its capsule form in infants under 5 years with cholestasis

## Public title

Design, production, and comparison of serum level of Ursodeoxycholic acid Nanoemulsion with its capsule form in infants under 5 years with cholestasis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Infants under 5 years with cholestasis

### Exclusion criteria:

Infants with noncompliant parents about blood sampling.  
Patients who are older than 5 year Infants with presurgery cholestasis.

## Age

To 5 years old

## Gender

Both

## Phase

Bioequivalence

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: 100

More than 1 sample in each individual

Number of samples in each individual: 3  
whole blood sampling

## Randomization (investigator's opinion)

Randomized

## Randomization description

Blocked randomized clinical trial. Block randomization works by randomizing participants within blocks such that an equal number are assigned to each treatment. This method is used to ensure a balance in sample size across groups over time. Blocks are small and balanced with predetermined group treatments, which keeps the numbers of subjects in each group similar at all times.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Participants and researchers are kept blind to the prescribed drug form (capsule or nanoemulsion). For blinding, the researcher in charge of sampling from each group, as well as the researcher in charge of drug analysis of samples, are unaware of how patients are placed in each of the groups, and the samples are coded after taking. Also, to blind the participants, capsule and nanoemulsion samples are given to them as a solution with a similar appearance.

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences, faculty of Medicine

##### Street address

Beside Taleghani Hospital, Arabi Ave, Yaman street, Velenjak, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

1983963113

#### Approval date

2021-03-02, 1399/12/12

#### Ethics committee reference number

IR.SBMU.MSP.REC.1399.774

## Health conditions studied

### 1

#### Description of health condition studied

CHOLESTASIS

#### ICD-10 code

K71.0

#### ICD-10 code description

Toxic liver disease with cholestasis

## Primary outcomes

### 1

#### Description

serum concentration of Ursodeoxycholic acid

#### Timepoint

0-1-3-5-12 and 24 hr after drug administration

#### Method of measurement

The blood samples taken from the study group were collected in heparinized tubes and after plasma separation, the plasma was frozen at a temperature of minus 20 ° C and the samples were stored. Samples will analyze by GC-Mass after one day. Calculation of pharmacokinetic factors, Cmax, AUC, Tmax is performed using GC-Mass analysis.

## Secondary outcomes

### 1

#### Description

serum concentration of Ursodeoxycholic acid

#### Timepoint

0-1-3-5-12-24 h after drug administration

## Method of measurement

The blood samples taken from the study group were collected in heparinized tubes and after plasma separation, the plasma was frozen at a temperature of minus 20 ° C and the samples were stored. Samples are analyzed by GC-Mass after one day.

## Intervention groups

### 1

#### Description

Intervention group: Infants with cholestasis. These children will receive Ursodeoxycholic acid nano emulsion that produced in Shahid Beheshti School of Pharmacy at a dose of 15 mg/kg/day, in three divided doses.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: These children will receive the contents of Ursodeoxycholic acid capsules produced in Koshan Pharmed Pharmaceutical Co. at a dose of 15 mg/kg/day, in three divided doses

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mofid children's hospital

##### Full name of responsible person

Dr. Naghi Dara

##### Street address

Shariati Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

15468155514

##### Phone

+98 21 2222 7021

##### Fax

+98 21 2222 0254

##### Email

Intl\_office@sbmu.ac.ir

##### Web page address

<http://www.mch.sbmu.ac.ir/>

### 2

#### Recruitment center

##### Name of recruitment center

Mahdieh Hospital

##### Full name of responsible person

Dr. Faeze Shojaei

## Street address

Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq

## City

Tehran

## Province

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## Postal code

1185817311

## Phone

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## Email

mahdiyeh\_hospital@sbmu.ac.ir

## Web page address

<http://www.sbmu.ac.ir/index.jsp?fkeyid=&siteid=110&pageid=15242>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr. Naghi Dara

##### Street address

Beside Taleghani Hospital, Arabi Ave, Daneshjoo Blvd, Velenjak

##### City

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##### Postal code

19839-63113

##### Phone

+98 21 2243 9770

##### Email

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Naghi Dara

**Position**

assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatric Gastroenterology

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Dr. Shariati

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Naghi Dara

**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Avina Pharmed Gostar Alborz

**Full name of responsible person**

Dr. Peyman Ghasemi

**Position**

Pharmacist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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**Province**

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**Phone**

+98 21 8860 3558

**Email**

Peyman.ghasemi@sbmu.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**

No - There is not a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The documents of this trial will be published in the form of an article after its completion.

**When the data will become available and for how long**

Access period starts 6 months after the results are published.

**To whom data/document is available**

Researchers, Pediatric Gastroenterologists, Pharmacists.

**Under which criteria data/document could be used**

Study design, referring, conferences.

**From where data/document is obtainable**

The journal of that article would be to publish, Pajohan database.

**What processes are involved for a request to access data/document**

Searching Clinical trial name in search engines.

**Comments**