Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluating the efficacy of ursodesoxy colic acid (ursobil) in reducing total serum bilirubin

Protocol summary

Summary

This is a randomized clinical trial to determine the efficacy of ursobil and phototherapy in decreasing neonatal hyperbilirubinemia. One hundred twenty neonates at ages 3-15 days with gestation ages more than 35 weeks who admitted for non-hemolytic neonatal jaundice, randomly allocate in three groups (each group 40 cases). In group A, neonates receive ursobil 10mg/kg in addition to phototherapy. Neonates in group B receive 15 mg/kg ursobil in addition to phototherapy. Patients in group C receive water and photo therapy.We evaluate and compare the rate of bilirubin decrease, the stool context (diarrhea, constipation), and other complications such as vomiting, feeding intolerance in three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701313915N18**
Registration date: **2017-02-11, 1395/11/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-11, 1395/11/23

Registrant information

Name

Manizheh Mostafa Gharehbaghi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1526 2253

Email address

peirovifara@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research vice chancellor of Tabriz University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy of ursodesoxy colic acid (ursobil) in reducing total serum bilirubin

Public title

Evaluating the efficacy of ursobil in reducing bilirubin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Birth weight more than 2500 grams; gestation age more than 35 weeks; age above 3 days less than 2 weeks; total serum bilirubin 14-20 mg/dl; direct bilirubin less than 2 mg/dl. Exclusion criteria: ABO incompatibility; Rh immunization; G6PDdefficiency; direct hyperbilirubinemia; sepsis; Crigler-Najjar syndrome; thyroid disorders; hepatic diseases; prematurity; infant of diabetic mother .

Age

From **3 days** old to **15 days** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of TabrizUniversity ofMedical Sciences

Street address

Golgasht street

City

Tabriz

Postal code

Approval date

2016-12-05, 1395/09/15

Ethics committee reference number

IR.TBZMED.REC.1395.928

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

The rate of bilirubin decrease

Timepoint

6,12,24 and 48 hours after starting treatment

Method of measurement

Measurment of total serum bilirubin

Secondary outcomes

1

Description

The duration of hospitalization

Timepoint

From admission til discharge

Method of measurement

The hours and days of admission

Intervention groups

1

Description

Internention group A recieve dissolved oral ursobil 10mg/kg in addition to phototherapy

Category

Treatment - Drugs

2

Description

Intervention group B recieve dissolved oral ursobil 15mg/kg in addition to phototherapy

Category

Treatment - Drugs

3

Description

Control group recieve water plus phototherapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children hospital

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research vice chancellor of Tabriz University of Medical Sciences

Full name of responsible person

Dr Rashidi

Street address

Golgasht street

City

Tabriz

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research vice chancellor of Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Afsane Mokhaleg Sani
Position
resident of pediatrics
Other areas of specialty/work
Street address
Sheshgelan street
City
Tabriz
Postal code
Phone
+98 41352662257
Fax
Email
gharehbaghimm@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Manizheh Mostafa Gharehbaghi. M.D.
Position
Professor of Pediatrics
Other areas of specialty/work
Street address
Sheshgelan street
City
Tabriz
Postal code
Phone
+98 41352662257
Fax
Email
gharehbaghimm@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Afsane Mokhaleg Sani. M.D.
Position
Other areas of specialty/work
Street address
Sheshgelan street
City
Tabriz
Postal code
Phone
00
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty