Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A prospective study on the effect of ursodeoxycholic acid on breast milk jaundice in neonate

Protocol summary

Summary

Jaundice is a common problem during neonatal period.The aim of this study is to evaluate the effect of ursodeoxycholic acid on breast milk jaundice. This study is a double-blind, randomized clinical trial that is conducted on neonates with breast milk jaundice (inpatient or outpatient) in hospitals affiliated to Shiraz University of Medical Sciences in 2017 that treat with phototherapy. Infants are randomly divided into two groups of 40, the patient group treat with phototherapy (home or hospital) and Ursobil 10 mg/kg/day (capsule 300 mg) orally divides every 12 hours. The drug is given to them by a pharmacist. The control group include 40 infants who receive placebo (distilled water) and phototherapy (home or hospital). Total bilirubin level is measured 12, 24 and 48 hours after phototherapy until bilirubin levels fall below 12 and phototherapy is discontinued. Two groups are compared in terms of total bilirubin levels at different times and during phototherapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017013028154N1**
Registration date: **2017-06-11, 1396/03/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-11, 1396/03/21

Registrant information

Name

Nader Shakibazad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-02-03, 1395/11/15

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A prospective study on the effect of ursodeoxycholic acid on breast milk jaundice in neonate

Public title

Effect of ursodeoxycholic acid on breast milk jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: birth weights 2500 to 4000 gram; being exclusively breastfed; gestational age of 38 to 41 weeks; age more than 7 days old; total bilirubin level of 14 to 20 mg/dL; direct bilirubin level less than 2 mg/dL. Exclusion criteria: infants with ABO and RH incompatibility; glucose 6-phosphate dehydrogenase deficiency; direct hyperbilirubinemia; septicemia; diseases leading to hyperbilirubinemia (Crigler-Najjar syndrome, gilbert syndrome, hypothyroidism and hyperthyroidism, liver diseases, premature neonates and the infants of diabetic

mothers)

Age
From **7 days** old to **1 month** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The method of randomization is the four-block method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Zand Street, Central building of Shiraz University of Medical Sciences, Shiraz, Iran

City
Shiraz

Postal code
7134814336

Approval date
2015-03-21, 1394/01/01

Ethics committee reference number
94-01-01-8985

Health conditions studied

1

Description of health condition studied
Breast milk jaundice

ICD-10 code
P59.3

ICD-10 code description
Neonatal jaundice from breast milk inhibitor

Primary outcomes

1

Description
Total bilirubin level

Timepoint
Before intervention, 12, 24 and 48 hours after intervention

Method of measurement
mg/dl

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group includes 40 neonates with breast milk jaundice that treat with phototherapy (home or hospital) and URSODEOXYCHOLIC ACID 10 mg/kg/day (CAPSULE ORAL 300 mg) orally divides every 12 hours. The drug is given to them by a pharmacist. Total bilirubin level is measured 12, 24 and 48 hours after phototherapy until bilirubin levels fall below 12 and phototherapy is discontinued. Two groups are compared in terms of total bilirubin levels at different times and duration of phototherapy. Written informed consent is taken from patients before the study. The URSODEOXYCHOLIC ACID is in capsule form 300 mg from Pharmaceutical Co. Alborz Darou. The drug is given to neonate by a pharmacist in a dose of 10 mg/kg divided two times in a day and there is no interaction between feeding and this drug.

Category
Treatment - Drugs

2

Description
Control group: The control groups include 40 infants who receiving placebo (distilled water) and phototherapy (home or hospital). Total bilirubin level is measured 12, 24 and 48 hours after phototherapy until bilirubin levels fall below 12 and phototherapy is discontinued. Two groups are compared in terms of total bilirubin levels at different times and duration of phototherapy. Written informed consent is taken from patients before study

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hafez, Nemazee and Zainebie hospitals of Shiraz University of Medical Sciences

Full name of responsible person
Maryam Nasri Lari
Street address
Nemazee hospital, department of neonatology, Shiraz, Iran
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyed Basir Hashemi, Vice chancellor for research of Shiraz University of Medical Sciences
Street address
Zand Street, Research center, Central building of Shiraz University of Medical Sciences, Shiraz, Iran
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Nasri Lari
Position
Neonatologist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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