Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A prospective study on The additive effect of ursodeoxycholic acid on indirect hyperbilirubinemia in neonate under phototherapy

Protocol summary

Summary

Hyperbilirubinemia is a common problem during infancy.Typically, phototherapy is used for reducing bilirubin in neonates; however, it has disadvantages.Therefore, the present study aims to investigate the effect of ursodeoxycholic acid on reducing the indirect bilirubin of the infants undergoing phototherapy; so that their lengths of phototherapy and hospitalization can be reduced. The present randomized clinical trial was conducted on the infants with hyperbilirubinemia who were under treatment by phototherapy in the neonatal wards of the hospitals affiliated to Shiraz University of Medical Sciences, Shiraz ,IRAN. Study design is interventional, randomaized, single blind.The infants are randomly divided into two 40-subject. The first group which include 40 infants with hyperbilirubinemia receive 10-15 mg/kg/day q12h ursodeoxycholic acid, while the control group receive no medications and only underwent phototherapy. The inclusion criteria of the study are birth weight of 2500-4000 g; being exclusively breast fed; gestational age of 38-41 weeks; being above 3 days old; total bilirubin level of 14-20, and direct bilirubin level<2 mg/dL. On the other hand, the infants with hemolysis & septicemia and the infants of diabetic mothers exclude from the study. Indirect bilirubin levels measure 2 time per day until the bilirubin level reache below 10 and phototherapy disrupte. The length of phototherapy measure using a timer. Finally the two groups are compared from the time bilirubin reache below 10, and length of phototherapy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020512370N1**
Registration date: **2013-05-12, 1392/02/22**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-05-12, 1392/02/22

Registrant information

Name
Narjes Pishva
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 1627 0182
Email address
ghashghaei@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A prospective study on The additive effect of ursodeoxycholic acid on indirect hyperbilirubinemia in neonate under phototherapy

Public title

A prospective study on The additive effect of ursodeoxycholic acid on indirect hyperbilirubinemia in neonate under phototherapy

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: birth-weight 2500-4000 gr; gestational age between 38-41 weeks; breastfeeding neonate; total bilirubin 14-20 mg/dl and neonates age older than three days. Exclusion criteria: infants with incompatible ABO, Rh; G6PD deficiency; direct hyper billirubinemia; septicemia or diseases that are implicated in causing jaundice; premature infants; infants of diabetic mothers.
Age
From **3 years** old to **28 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
shiraz university of medical science
Street address
shiraz university of medical scienc,zand street,shiraz
City
shiraz
Postal code
71438-14336
Approval date
2012-09-20, 1391/06/30
Ethics committee reference number
CT-P-91-3827

Health conditions studied

1

Description of health condition studied
Indirect hyperbilirubinemia in neonate
ICD-10 code
P59.9
ICD-10 code description
Physiological jaundice (intense)(prolonged) NOS

Primary outcomes

1

Description
Duration of need phototherapy
Timepoint
Since start study till finish study
Method of measurement
Timer

Secondary outcomes

1

Description
Serum total bilirubin
Timepoint
Since start study &12, 24, 36, 48 hour
Method of measurement
Blood sample

Intervention groups

1

Description
First group was given ursodeoxycholic acid 10-15 mg/kg divided q12h before starting phototherapy till exclusion from study. In the first day, laboratory tests included estimation of total bilirubin (direct and indirect), blood group including rh of the mother and neonate, complete blood count (cbc), g6pD activity, coombs test, reticulocyte count. Direct and indirect, as well as tsb were measured every 24 hours by the same laboratory till total serum bilirubin dropped under 10 mg/dl. The duration of phototherapy was recorded with a timer.
Category
Treatment - Drugs

2

Description
Second group that is control group received no medications and only underwent phototherapy.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez hospital
Full name of responsible person
Ghashghaei Saadi Elham MD

Street address
Phototherapy ward, Hafez hospital, Chamran blud square, Daneshjo square
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hatam Gholamreza MD
Street address
Shiraz University of Medical Science, Zand street, Shiraz
City
Shiraz
Grant name
ردیف بودجه طرح های تحقیقاتی
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Ghashghaei Saadi Elham MD
Position
MD, resident of pediatric disease
Other areas of specialty/work
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Pediatric office ward, Namazi hospital
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Honar Naser MD
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Asistant professor of pediatric gasteroenterology
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Person responsible for updating data

Contact
Name of organization / entity
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MD, resident of pediatric disease
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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