Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effects of Silymarin in the treatment of idiopathic hyperbilirubinemia:a randomized,double-blind, placebo-controlled, clinical trial

Protocol summary

Study aim
Determining the effect of oral extract of silymarin in the treatment of neonatal hyperbilirubinemia

Design
Clinical trial with control and intervention groups, with parallel groups, double-blind, randomized. Random Allocation Software is used for randomization. Sample size 60 neonates, 30 in each group.

Settings and conduct
Term neonates admitted due to jaundice in NICU of Mashhad Ghaem Hospital randomly divided into two groups. One group is given 4 mg per kg of silymarin oral extract twice daily for two days from the first day of phototherapy and control group is prescribed placebo, which is distilled water, in the same amount and frequency. Serum bilirubin is measured at 6, 12, 24 and 48 hours.This is a double- blind study and parents and researchers do not know the type of drug and the drug is coded as A and B.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Healthy infants 2 to 10 days old with icter who meet the AAP criteria for the treatment of hyperbilirubinemia with phototherapy. Exclusion criteria: parental dissatisfaction, blood incompatibility, underlying disease

Intervention groups
In the intervention group, in addition to phototherapy, infants received 4 mg per kilogram of oral silymarin at a concentration of 4 mg per cc prepared at the Medicinal Plants Research Center of Mashhad University of Medical Sciences every 12 hours from the first day of hospitalization. Serum bilirubin levels are measured 6, 12, 24 and 48 hours after the start of treatment. In the control group, placebo, which is distilled water, is prescribed in the same amount and frequency as the intervention group (one cc per kg of body weight) and serum bilirubin is measured 6, 12, 24 and 48 hours after the start of treatment.

Main outcome variables
serum bilirubin levels; duration of phototherapy; length of hospital stay

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211122053144N1**
Registration date: **2022-01-02, 1400/10/12**
Registration timing: **prospective**

Last update: **2022-01-02, 1400/10/12**
Update count: **0**

Registration date
2022-01-02, 1400/10/12

Registrant information

Name
Sara Mohammadzadeh Rezaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3840 8539

Email address
mohammadzadehrs991@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-10, 1400/10/20

Expected recruitment end date
2023-01-10, 1401/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of Silymarin in the treatment of idiopathic hyperbilirubinemia:a randomized,double-blind, placebo-controlled, clinical trial

Public title

Investigating the effects of Silymarin in the treatment of neonatal jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Term neonates who have the AAP criteria for the treatment of hyperbilirubinemia with phototherapy Healthy term neonates who have jaundice from the 2nd to the 10th day of birth and need phototherapy

Exclusion criteria:

Neonates with bilirubin level in range of blood exchange The neonate or mother has received phenobarbital Neonates with dehydration, sepsis, pneumonia, anemia, severe weight loss, hypoglycemia, renal failure, heart failure, possible hemolytic or inherited hemolytic disease, neonates with conjugated hyperbilirubinemia, neonates with G6PD, ABO or Rh incompatibility Neonates with a history of jaundice medication from two days before

Age

From **2 days** old to **10 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple Randomization tool: closed envelope Allocation Concealment: sealed envelopes containing random and equal sequence contents from two intervention and control groups

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study in which the researcher and the patient do not know about the type of drug. Drugs and placebos are exactly the same in shape, color, smell, and glass, and are codenamed A and B. After collecting the data, the codes are opened and the drug and placebo are identified

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Azadi Square, east door of the university campus

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2021-09-07, 1400/06/16

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.467

Health conditions studied

1

Description of health condition studied

Neonatal jaundice

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

serum bilirubin

Timepoint

24,48 and 72 hours after starting phototherapy

Method of measurement

bilirubin kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, in addition

to phototherapy, neonates receive from the first day of hospitalization at the rate of 4 mg per kg of body weight every 12 hours oral drops of silymarin with a concentration of 4 mg per cc prepared at the Medicinal Plants Research Center of Mashhad University of Medical Sciences. Serum bilirubin levels are measured 6, 12, 24 and 48 hours after the start of treatment.

Category

Treatment - Drugs

2

Description

Control group: In the control group, in addition to phototherapy, infants receive an equal amount of placebo (distilled water) from the first day of hospitalization. Serum bilirubin levels are measured 6, 12, 24 and 48 hours after the start of treatment.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Ghaem hospital

Full name of responsible person

Sara Mohammadzadeh Rezaei

Street address

Dr. Shariati Square, Ahmadabad Street

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

Street address

Ghoreshi Building, next to Hoveyzeh cinema, Daneshgah Street

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Sara Mohammadzadeh Rezaei

Position

Neonatology fellowship

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Neonatal intensive care unit, Ghaem hospital, Dr. Shariati Square, Ahmadabad St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Gholam Ali Maamouri

Position

Professor

Latest degree
Subspecialist
Other areas of specialty/work
Neonatologist
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Neonatal intensive care unit, Ghaem hospital, Dr. Shariati Square, Ahmadabad St.
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Person responsible for updating data

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Sara Mohammadzadeh Rezaei
Position
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Other areas of specialty/work
Pediatrics
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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
Yes - There is 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
All data can be shared after patients are made unidentifiable.
When the data will become available and for how long
Data can be accessible 6 months after results are published.
To whom data/document is available
Data will be available for researchers in universities and other scientific institute
Under which criteria data/document could be used
After publication as an article, it can be used by the public and researchers of medical universities
From where data/document is obtainable
Data can be accessible through an email to the corresponding author. Email: mohammadzadehrs991@mums.ac.ir
What processes are involved for a request to access data/document
After sending a request email to the corresponding author, data will be sent in 1 month.
Comments