

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

<https://quaem.mums.ac.ir>

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 Hoveyze 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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Person responsible for updating data

Contact

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Full name of responsible person
Sara Mohammadzadeh Rezaei
Position
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Latest degree
Specialist
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