Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

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

Design
A clinical trial with a control and intervention group, parallel-group design, double-blind, randomized, using Random Allocation Software for randomization. The sample size is 120 newborns, with 60 newborns in each group.

Settings and conduct
The full-term newborns will receive silymarin and placebo drops for 4 days from birth. Bilirubin levels will be measured using TCB for 4 days, and serum bilirubin will be checked as needed, either in the maternity ward or during outpatient NICU visits at Ghaem Hospital for jaundice evaluation.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Full-term newborns who are negative for the Coombs test at birth, Healthy full-term newborns who do not require phototherapy, Newborns whose bilirubin levels are not in the range requiring blood exchange, Newborns with no history of the mother taking any kind of medication during pregnancy. Exclusion Criteria: Newborns with RH incompatibility who are positive for the Coombs test, Newborns with an increase in bilirubin to the level requiring blood exchange, Newborns requiring phototherapy on the first day of birth, Deterioration in the newborn's condition during hospitalization with dehydration, sepsis, pneumonia, anemia, severe weight loss, hypoglycemia, renal failure, or heart failure, Newborns with a history of the mother taking any kind of medication during pregnancy, Newborns or mothers who have received phenobarbital, Newborns who experience severe drug reactions following the use of silymarin, Parents' refusal to continue treatment.

Intervention groups
Healthy full-term newborns from the first day of birth who receive 4 mg per kilogram of weight of oral silymarin drops three times a day for 4 days from birth.

Main outcome variables
jaundice in the first three days after birth

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231120060123N1**
Registration date: **2023-11-21, 1402/08/30**
Registration timing: **prospective**

Last update: **2023-11-21, 1402/08/30**
Update count: **0**

Registration date
2023-11-21, 1402/08/30

Registrant information

Name
Hamidreza Goldouzi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3845 3239

Email address
goldouzihr4011@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-12-21, 1403/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effects of Silymarin in the Prevention of hyperbilirubinemia: a randomized, double-blind, placebo-controlled, clinical trial

Public title
effects of Silymarin in the Prevention of hyperbilirubinemia
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Full-term newborns who are negative for the Coombs test at birth. Healthy full-term newborns who do not require phototherapy. Newborns whose bilirubin levels are not in the range requiring blood exchange. Newborns with no history of the mother taking any kind of medication during pregnancy.
Exclusion criteria:
Newborns with RH incompatibility who are positive for the Coombs test. Newborns with an increase in bilirubin to the level requiring blood exchange. Newborns requiring phototherapy on the first day of birth. Deterioration in the newborn's condition during hospitalizationwith dehydration, sepsis, pneumonia, anemia, severe weight loss, hypoglycemia, renal failure, or heart failure. Newborns with a history of the mother taking any kind of medication during pregnancy or mothers who have received phenobarbital. Newborns who experience severe drug reactions following the use of silymarin. Parents' refusal to continue treatment.
Age
From **2 days** old to **10 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **120**
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
2023-09-19, 1402/06/28
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1402.357

Health conditions studied

1

Description of health condition studied
Neonatal jaundice, unspecified
ICD-10 code
P59.9
ICD-10 code description
Neonatal jaundice, unspecified

Primary outcomes

1

Description
Transcutaneous bilirubin level
Timepoint
24,48 and 72 hours after birth
Method of measurement
Bilichek device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, newborns receive oral silymarin drops from the first day of birth at a dose of 4 mg per kilogram of body weight every 12 hours. The silymarin, with a concentration of 4 mg per cc, is prepared by the Medicinal Plants Research Center of Mashhad University of Medical Sciences. The transcutaneous bilirubin level will be measured 24, 48, and 72 hours after the start of treatment.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad Ghaem hospital

Full name of responsible person
Hamidreza Goldouzi

Street address
Dr. Shariati Square, Ahmadabad Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9176699199

Phone
+98 51 3801 2502

Email
GoldouziHR4011@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Street address
Ghoreshi Building, next to Hoveyzeh cinema, Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

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9138813944

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+98 51 3841 1538

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vcresraech@mums.ac.ir

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
Hamidreza Goldouzi

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.

City
Mashhad

Province
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Postal code
9176699199

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+98 51 3801 2502

Email
GoldouziHR4011@mums.ac.ir

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
Pediatrics

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

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maamourigh@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamidreza Goldouzi

Position

Neonatology fellowship

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

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Email

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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.

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