

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the effect of oral Medium-Chain Triglyceride oil in the treatment of hyperbillirubinemia in term neonates

Protocol summary

Study aim

The effect of medium chain triglyceride oil in the treatment of neonatal jaundice

Design

74 neonates will be divided into two groups ,37 neonates in intervention group , 37 neonates in Control group. This study is a clinical trial ,double blind, simple randomized(computer randomization list) , phase 3.

Settings and conduct

Infants admitted to Imam Reza Hospital in Mashhad with a gestational age of more than 37 weeks, birth weight of more than 2500 grams, which are indicated for phototherapy are included in the study. With the help of computer randomization list, they are divided into two groups. One group is prescribed triglyceride oil (intervention) and the control group is prescribed distilled water (placebo). It is a double blind study in which 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: gestational age more than 37 weeks, birth weights more than 2500 grams and indication of phototherapy. Exclusion Criteria: Blood group and RH incompatibility, Low Apgar, subgaleal hemorrhage, cephal hematoma, congenital anomaly, infection, gastrointestinal obstruction and cholestasis, heart failure , renal failure, blood exchange .

Intervention groups

interventional group will receive Medium-Chain Triglycerides (Nutricia) orally 3 cc / kg as a single dose. control group will receive placebo(distilled water) orally 3 cc/kg as a single dose.

Main outcome variables

serum bilirubin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001162N26**

Registration date: **2020-11-21, 1399/09/01**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-21, 1399/09/01**

Update count: **0**

Registration date

2020-11-21, 1399/09/01

Registrant information

Name

Ashraf Mohammadzadeh

Name of organization / entity

Neonatal Research Center of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1852 1121

Email address

mohamadzadeha@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral Medium-Chain Triglyceride oil in the treatment of hyperbillirubinemia in

term neonates

Public title
Effect of triglyceride oil on the treatment of neonatal jaundice

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 gestational age more than 37 weeks Birth weight more than 2500 grams Indication of phototherapy
Exclusion criteria:
 Congenital anomaly infection Gastrointestinal obstruction and cholestasis Heart failure blood exchange Renal failure blood group or Rh incompatibility Low Apgar Subgaleal hemorrhage Cephal hematoma

Age
From **1 day** old to **30 days** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple randomization method is used. This method is done through a table of random numbers using the site www.randomization.com. The numbers are placed in sealed envelopes and with the arrival of patients, an envelope is assigned to each of them, which will be placed in one of the two 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 and the drug is coded as 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
Ghoreyshi Bul, Daneshgah Ave, Doctora Intersection, Mashhad-Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Approval date
2019-07-23, 1398/05/01

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1398.215

Health conditions studied

1

Description of health condition studied

hyperbillirubinemia in term neonates

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Indirect serum bilirubin levels

Timepoint

On admission and at 24, 48, 72 hours later and if necessary the following days

Method of measurement

skin bilirubin meter and blood sample (if necessary)

Secondary outcomes

1

Description

Daily weight information

Timepoint

Hospitalization

Method of measurement

scale

Intervention groups

1

Description

interventional group will receive Medium-Chain Triglycerides (Nutricia) orally 3 cc / kg as a single dose.

Category

Treatment - Drugs

2

Description

control group will receive placebo(distilled water) orally 3 cc / kg as a single dose.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Ezzat Khodashenas

Street address

Imam Reza Hospital- Ibn Sina Ave-Mashhad-Iran

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+98 51 3852 1121

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nrc@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

Central Building of Mashhad university of Medical sciences (Ghorshi), Daneshgah 16, 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

Ezzat Khodashenas

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be 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 can be accessible through an email to the corresponding author

Under which criteria data/document could be used

Data will be available for researchers in universities and other scientific institute.

From where data/document is obtainable

After sending a request email to the corresponding author, data will be sent in 1 month.

What processes are involved for a request to access data/document

Carrying out analysis on data is permitted.

Comments