

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of the effect of oral Medium-Chain Triglycerides oil in healthy Late preterm infants in the prevention of icter

Protocol summary

Study aim

Effect of oral triglyceride oil on prevention of preterm neonatal jaundice

Design

preterm neonates with 36-34 weeks of gestational age that born in Imam Reza Hospital, were randomly divided into two groups of 40 in the control group and 40 in the case group. Gestational age - Birth weight - Daily weight information - Number of temperaments and bilirubin levels to be checked by skin bilirubin check during the first 5 days. The infant of the case group will be given an oral solution of triglyceride with a medium chain of one cc per kilogram of body weight during the first day of birth. Daily bilirubin was measured by a skin bilirubin control device from the frontal area and on the bone of the sternum and the daily mean of two was calculated.

Settings and conduct

Newborns with gestational age of 36-34 weeks born in Imam Reza Hospital in Mashhad, birth weight of more than 2500 grams that are indicated by phototherapy are included in the study and divided into two groups by simple randomization list. Medium chain triglyceride oil will be given to case group and placebo will be given to control group(sterile distilled water). The study is a double-blind study that the researcher and the patient are not aware of the type of drug.

Participants/Inclusion and exclusion criteria

Entry requirements: Preterm infant 34-36 weeks gestation age Exclusion criteria: ABO or Rh incompatibility, low apgar, Subglacial bleeding, cephal hematome, Congenital anomaly, infection, Gastrointestinal and cholestatic obstruction

Intervention groups

In the intervention group, the infant is fed one cc of MCT oil per kg body weight plus breast milk. In the control group, breast feeding is normally performed only with breast milk.

Main outcome variables

Effect of mct oil on prevention of neonatal jaundice

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081021001378N12**

Registration date: **2020-10-04, 1399/07/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-04, 1399/07/13**

Update count: **0**

Registration date

2020-10-04, 1399/07/13

Registrant information

Name

Ahmadshah Farhat

Name of organization / entity

Neonatal Research Center of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 1121

Email address

farhata@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of oral Medium-Chain Triglycerides oil in healthy Late preterm infants in the prevention of icter

Public title

Effect of triglyceride oil on prevention of neonatal jaundice

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Preterm infant 34-36 weeks gestation age

Exclusion criteria:

ABO or Rh incompatibility Cephalhematoma Low apgar
Subglacial bleeding Congenital anomaly Infection

Age

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

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be carried out using table of random numbers available at 'www.randomization.com' website where the produced numbers are placed in sealed envelopes assigning each patient to one of the two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This a double blind study in which the researcher is not aware of the type of medicine and time intervals. Also the patients' parents are unaware of the time intervals but they know about the type of medicine that is to be used.

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

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2019-05-21, 1398/02/31

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.362

Health conditions studied**1****Description of health condition studied**

hyperbilirubinemia in term neonates

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

transcutaneous bilirubin levels

Timepoint

During the first 5 days after birth

Method of measurement

Using Transcutaneous bilirubin meter - JH20-1A by NINGBO DAVIS MEDICAL Company

2**Description**

Daily weight information

Timepoint

Before the intervention, on the first day and 2 days after commencement of the study

Method of measurement

Clinical observation

3**Description**

Number of defecation

Timepoint

Before the intervention, on the first day and 2 days after commencement of the study

Method of measurement

Clinical observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Infants fed one cc of MCT oil per kg body weight plus breast milk on the first day of birth

Category

Lifestyle

2

Description

Control group: Normal feeding is only with breast milk

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Saeed Esmaeili

Street address

Neonatal Intensive Care Unite, Imam Reza Hospital, Ibn Sina Ave, Mashhad, Iran

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9137913316

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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

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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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9177899191

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ramresearch@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

Saeed Esmaeili

Position

Neonatology

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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 institutes.

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