Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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Iran (Islamic Republic of)
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+98 51 3852 1121
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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
hyperbillirubinemia in term neonates
ICD-10 code
ICD-10 code description

Primary outcomes

1

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

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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