Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Docosahexaenoic Acid Supplementation on neonatal outcomes of pereterm infants

Protocol summary

Study aim
Effect of Docosahexaenoic Acid Supplementation on neonatal outcomes of pereterm infants at Mahdieh,Arash and Imam Hossein Hospitals

Design
Participating infants will be randomly assigned to two groups.Regarding that the medicinal products and placebo have already been coded by the clinical pharmacist, the doctor and nurse in charge of the patient will not know the nature of the product. The estimated sample size is: 384 patient.

Settings and conduct
The participated neonates divided in two groups receiving DHA and placebo. When the received milk reached 50 cc/kg/day,,intervention with 0.5 cc/kg/day of the prepared drug solution and placebo will be prescribed and the neoonates will be compared i

Participants/Inclusion and exclusion criteria
inclusion criteria:: Premature babies with a gestational age of < 34 weeks and weighing <2000 grams.exclusion criteria:infants who are candidates for extensive surgeries, extensive congenital abnormalities, platelets count <80,000/mm3, discharge earlier than 14 days, special treatment regimen for the mother, feeding with a formula containing DHA in the infant, lack of parental consent

Intervention groups
The infants included in the study are preterm infants who can tolerate enteral feeding with the minimum considered volume and will be able to tolerate nutritional supplementation.

Main outcome variables
Determining the effect of doxohexanoic acid on the growth indices of premature babies in Mofid, Mahdia, Arash and Imam Hossein (AS) Children's Hospital.

General information

Reason for update

Acronym
DHA

IRCT registration information
IRCT registration number: **IRCT20221120056556N2**
Registration date: **2023-01-28, 1401/11/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-28, 1401/11/08**
Update count: **0**

Registration date
2023-01-28, 1401/11/08

Registrant information

Name
Minoo Fallahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2222 7021

Email address
minoofallahi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

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

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Docosahexaenoic Acid Supplementation on neonatal outcomes of pereterm infants

Public title
Effect of Docosahexaenoic Acid Supplementation on neonatal outcomes of pereterm infants
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Preterm infants with gestational age less than 34 weeks. Birth weight less than 2000 gr.
Exclusion criteria:
Infants need to major surgery Infants with major congenital anomalies Exclusively formula fed infants Discharge to home on less than 14th day of life Infants of mother whit special treatment diet
Age
From **1 day** old to **30 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **384**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the block randomization method. This method should be used in order to create a balance in the number of samples allocated to each groups and it helps the researchers in cases where there is a need to perform analysis during the sampling process, the number of samples allocated to Each of the studied groups should be equal. In this trial, we will have two groups of 4 blocks (BAAB), (ABBA), (AABB), (BBAB), (ABAB) (including 2 participants in the doxohexanoic acid group and 2 participants in the placebo group). Randomization will also be done using random sequence generation software (random allocation software). Based on the list of randomly prepared blocks of four, a trained person (clinical pharmacologist) outside the research team is responsible for randomly allocating patients, after each patient is admitted to the special ward, according to the block of four prepared in the first stage. Each patient will be randomly assigned to A) intervention) or B) placebo group) and the sampling process will be carried out consecutively until the end of sampling, the code of each patient will also be assigned to his family member. People are assigned to the desired group in the order of their entry into the study and randomly through randomized blocks, and this process continues until the selection of the last block.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Products that encoded to drug and placebo by clinical pharmacist, will be prescribe for infants by blinded neonatologist. Then a blinded nurse will administrate the products. Our blinded coauthors who is responsible for outcome assessment and other statistical analyzer will be evaluate the outcomes and results.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
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Postal code
19839-63113
Approval date
2022-07-07, 1401/04/16
Ethics committee reference number
IR.SBMU.RICH.REC.1401.013

Health conditions studied

1

Description of health condition studied
Nutrition of premature babies / Growth of premature babies / Prognosis of premature babies
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Determining the effect of Docosahexaenoic acid on the growth indices of premature infants
Timepoint
During the study, the growth indices will be checked daily to measure weight and weekly to measure height and head circumference, and they will be checked until the time the baby is admitted to the hospital.
Method of measurement
A scale will be used to measure weight and a meter will be used to measure height.

Secondary outcomes

1

Description
Investigating the effect of Docosahexaenoic acid on the incidence of intraventricular hemorrhage in preterm infants
Timepoint
During the whole time of the baby's stay in the hospital
Method of measurement
With brain ultrasonography

2

Description
Investigating the effect of Docosahexaenoic acid acid acids on the incidence of neonatal sepsis in preterm infants
Timepoint
During the whole time of the baby's stay in the hospital
Method of measurement
Clinical finding and blood culture examination

3

Description
Investigating the effect of Docosahexaenoic acids on the incidence of neonatal necrotizing enteroculitis in preterm infants
Timepoint
During the whole time of the baby's stay in the hospital
Method of measurement
clinical and radiological findings

4

Description
Investigating the effect of Docosahexaenoic acids on the incidence of retinopathy of prematurity in preterm infants
Timepoint
During the whole time of the baby's stay in the hospital
Method of measurement
Based on the retinal exam by ophthalmologist

Intervention groups

1

Description
Intervention group:Premature babies are divided into intervention and placebo groups using a random number table. So that the people who met the conditions to enter the study will be treated by pre-coded pharmaceutical and placebo products prepared by the clinical pharmacist and the doctor and nurse of the ward have no knowledge of their original nature. The baby receives 60 cc/kg of milk enterally, starting and continuing for 14 days. If the baby is discharged from the ward earlier than 14 days, it will be excluded from the study. In both the intervention and control groups, available emulsions (including placebo and DHA) based on the weight of the baby with a dose of 0.5 cc/kg/day (as daily or every twelve hours based on the baby's tolerance) will be prescribed. During the daily visit, the request for the implementation of the intervention for 14 days will be included in the doctor's request sheet by the neonatologist. It will be given to the baby before feeding with breast milk and through gavage. It should be mentioned that DHA and placebo emulsion are similar in terms of color, volume and taste. Then, the growth indicators during the intervention period are daily and after completion. He will be evaluated weekly until he is discharged from the hospital and also after discharge in follow-up clinics on a monthly basis, and the relevant checklists will be completed.More about this source textSource text required for additional translation informationSend feedbackSide panels
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid Children Hospital
Full name of responsible person
Minoo Fallahi
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7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
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Recruitment center
Name of recruitment center
Mahdieh Hospital
Full name of responsible person
Minoo Fallahi
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Recruitment center

Name of recruitment center
Imam Hossein Hospital

Full name of responsible person
Minoo Fallahi

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Recruitment center

Name of recruitment center
Arash Hospital

Full name of responsible person
Minoo Fallahi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
افشین زرقی

Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Minoo Fallahi

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

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Position
Associate professor

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available