Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Docosahexaenoic Acid on prevention of retinopathy of prematurity in premature newborn

Protocol summary

Study aim
Determination of the effect of docosahexaenoic acid on the prevention of premature retinopathy in premature infants

Design
A clinical trial with parallel groups, double-blinded, randomized (permuted block randomization), phase 3 on 124 premature newborns, using www.sealedenvelope.com for randomization

Settings and conduct
This randomized clinical trial study was performed on 124 premature infants weighing less than 1500 g hospitalized in the intensive care unit of Akbarabadi Hospital and Ali Asghar Hospital in Tehran from March to December 2021. Newborns were randomly assigned into 2 groups. In the first intervention group, 1 cc of DHA supplement was prescribed daily for 1 month. In the placebo control group, 1 cc daily was prescribed for 1 month.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Obtaining parental consent to participate in the study, Premature newborn weighing less than1500 gr; Exclusion Criteria: Infants with asphyxia (umbilical cord pH less than 7 and BE less than -16), IUGR infants, Definitive sepsis (positive blood culture), Newborns with severe congenital chromosomal abnormalities, Newborns with congenital heart disease, Infants with metabolic diseases, Newborns with hypotension need vasodilators

Intervention groups
Intervention group: Infants took the DHA supplement (Kelvin kids Drop, manufactured by Zist Takhmir Company, Iran) orally (gavage or PO), 1 cc (40 mg) daily for 1 month. Control group: Newborns took 1 cc of distilled water daily (placebo made by Zist Takhmir Company with the same color and taste as DHA) orally (gavage or PO), 1 cc daily (40 mg) for 1 month.

Main outcome variables
Retinopathy stage (based on disease severity)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211226053528N1**
Registration date: **2022-01-31, 1400/11/11**
Registration timing: **retrospective**

Last update: **2022-01-31, 1400/11/11**
Update count: **0**

Registration date
2022-01-31, 1400/11/11

Registrant information

Name
Nastaran Khosravi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2304 6253

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khosravi.n@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-21, 1400/01/01

Expected recruitment end date
2021-12-22, 1400/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Effect of Docosahexaenoic Acid on prevention of retinopathy of prematurity in premature newborn

Public title
Effect of Docosahexaenoic Acid on ROP in premature newborn
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Obtaining parental consent to participate in the study Premature newborn weighing less than1500 gr
Exclusion criteria:
Infants with asphyxia (umbilical cord pH less than 7 and BE less than -16) IUGR infants Definitive sepsis (positive blood culture), Newborns with severe congenital chromosomal abnormalities Newborns with congenital heart disease Infants with metabolic diseases Newborns with hypotension need vasodilators
Age
From **1 day** old to **14 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **124**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the block randomization method was used with blocks of sizes six and four. The website https://www.sealedenvelope.com was used to create a randomization list. The blocks were randomly selected using this website and given to a researcher who was not involved in choosing the type of drug. Each random chain generated contains a unique code for concealment. The drug regimen was placed in envelopes according to random chains, and after sealing it on the envelopes, the specific number created by the site was written and the envelopes were randomly placed in a box.
Blinding (investigator's opinion)
Double blinded
Blinding description
blinding patients: Infants were not aware of the type of medication received due to their condition Physician blinding: DHA and distilled water (with the same color and taste as DHA) are both oral and given to the newborn by gavage.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences,5th Floor, Hemat Highway, Next to the Milad Tower
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2021-02-13, 1399/11/25
Ethics committee reference number
IR.IUMS.FMD.REC.1399.842

Health conditions studied

1

Description of health condition studied
Retinopathy of prematurity
ICD-10 code
H35.1
ICD-10 code description
Retinopathy of prematurity

Primary outcomes

1

Description
Retinopathy stage (based on disease severity)
Timepoint
before intervention and 1month after intervention
Method of measurement
Based on the severity of the disease (1-5 stages) by an ophthalmologist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Infants took the DHA supplement (Kelvin kids Drop, manufactured by Zist Takhmir Company, Iran) orally (gavage or PO), 1 cc (40 mg) daily for 1 month.
Category
Prevention

2

Description
Control group: Newborns took 1 cc of distilled water daily (placebo made by Zist Takhmir Company with the same color and taste as DHA) orally (gavage or PO), 1 cc daily (40 mg) for 1 month.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Akbarabadi Hospital

Full name of responsible person
Fatemeh Jafarnazari

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Molavi St, Molavi (cross)

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2

Recruitment center

Name of recruitment center
Aliasghar Children's Hospital

Full name of responsible person
Fateme Jafarnazari

Street address
No. 193, Vahid dastgerdy Ave, Modares highway, Aliasghar Children Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Fateme Jafarnazari

Position
Fellow

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

Contact

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Position
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Latest degree
Specialist

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Person responsible for updating data

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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
Not applicable

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