

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 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 than 1500 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)

Phone

+98 21 2304 6253

Email address

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 than 1500 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 1 month 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

Street address

Molavi St, Molavi (cross)

City

Tehran

Province

Tehran

Postal code

۱۱۶۸۷۴۳۵۱۴

Phone

+98 21 5560 6034

Email

fatemejafarnazari@gmail.com

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

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6253

Email

fatemejafarnazari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Hosein Keivani

Street address

Shahid Hemmat Highway next to the Milad tower, Iran
University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8671

Email

keivani.h@iums.ac.ir

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

Street address

Aliasghar Children's Hospital, No.193, Modares
Highway, zafar St

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6253

Fax

Email

khosravi.n@iums.ac.ir

Person responsible for scientific 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

Street address

Aliasghar Children's Hospital, No.193, Modares Highway, zafar St

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6253

Fax**Email**

khosravi.n@iums.ac.ir

Person responsible for updating data

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

Street address

Aliasghar Children's Hospital, No.193, Modares Highway, zafar St

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6253

Fax**Email**

khosravi.n@iums.ac.ir

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