

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of omega-3 and zinc supplementation in the prevention of Retinopathy Of Prematurity (ROP) : a double-blind clinical trial

Protocol summary

Study aim

Investigating the effectiveness of adding oral omega-3 and zinc to the diet of premature neonates in preventing the occurrence of retinopathy of prematurity (ROP).

Design

A clinical trial with a control group, double-blind, randomized by block method, phase 3, on 300 patients.

Settings and conduct

Premature neonate are fed 250 mg of omega-3 supplements for 28 days. In the zinc group, the amount of zinc in the oral supplement will be increased to 2 mg/kg. In the Omega 3 and Zinc groups, they receive the same dose as the previous two groups. In the placebo group, feeding is done with normal saline serum.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Premature neonates with a gestational age of less than 32 weeks - Premature neonates with a birth weight of less than 1500 grams - Breast feeding ;
Exclusion criteria: Major congenital anomalies - Sepsis or significant comorbidities

Intervention groups

In this study, the infants included in the study were in one of the four enteral feeding groups with a high dose of omega-3 (omega-3 group), a high-dose zinc group (zinc group), and a group fed with omega-3 and zinc (omega-3 and zinc group). The group fed with placebo (control group) will be placed

Main outcome variables

The primary outcome is the incidence of ROP requiring treatment, which will be by regular ophthalmological examinations with an ophthalmoscope according to the modified protocol at 1 month of age and every 2 weeks thereafter at the physician's discretion. Secondary outcomes include severity of ROP, need for laser therapy or surgery, and visual acuity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180404039187N12**

Registration date: **2023-11-19, 1402/08/28**

Registration timing: **prospective**

Last update: **2023-11-19, 1402/08/28**

Update count: **0**

Registration date

2023-11-19, 1402/08/28

Registrant information

Name

Elnaz Shaseb

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 1337 2250

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of omega-3 and zinc supplementation in the prevention of Retinopathy Of Prematurity (ROP) : a double-blind clinical trial

Public title

The effect of omega-3 and zinc supplementation in the prevention of retinopathy of prematurity

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Premature neonates with a gestational age of less than 32 weeks
Premature neonates with a birth weight of less than 1500 grams
Breast feeding

Exclusion criteria:

Major congenital anomalies
Sepsis or significant comorbidities

Age

From **1 day** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by block method with blocks of 4 and 8 and we will have 3 intervention groups and 1 control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and the researcher are blind during the study. Blinding will be done in such a way that the patients and the researcher do not know whether they are in the control group or the intervention group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz university of medical sciences

Street address

Research and technology dept, central building No.2, third floor, tabriz university of medical sciences, golgasht St, tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2023-10-23, 1402/08/01

Ethics committee reference number

IR.TBZMED.PHARMACY.REC.1402.037

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

The occurrence of ROP requires treatment

Timepoint

28 days after birth

Method of measurement

Regular ophthalmology examinations with an ophthalmoscope according to the protocol and based on the diagnosis of the stage and zone of the disease by the doctor

Secondary outcomes

1

Description

including severity of ROP, need for laser therapy or surgery, and visual acuity

Timepoint

According to the doctor's opinion, every 2 weeks

Method of measurement

Regular ophthalmology examinations with an ophthalmoscope according to the protocol and based on the diagnosis of the stage and zone of the disease by the doctor

Intervention groups

1

Description

Intervention group: Enteral feeding group with Omega 3

Category

Prevention

2

Description

Intervention group: Enteral feeding group with zinc

Category

Prevention

3

Description

Intervention group: Enteral feeding group with zinc and omega 3

Category

Prevention

4

Description

Control group: enteral feeding group with placebo

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Elnaz Shaseb

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Parviz Shahabi

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Elnaz Shaseb

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

clinical pharmacy

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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