

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of zinc and omega-3 supplementation effect on maternal and fetal outcomes in pregnant women with IUGR fetus with control group, a double-blind placebo controlled clinical trial study

Protocol summary

Study aim

The effect of zinc and omega-3 supplementation in pregnant women with IUGR embryos on maternal and fetal outcomes

Design

Randomized, superiority, parallel group trial design of 117 patients with blinded outcome assessment. Randomization with block randomization method,

Settings and conduct

This double-blind clinical trial study was performed on pregnant women referring to the gynecology and maternity clinic of Sayad Shirazi Hospital, Gorgan, with US based on IUGR embryo and between 28-30 weeks of gestation in 2020.

Participants/Inclusion and exclusion criteria

Pregnant women aged 18-35 years Pregnant women with a gestational age of more than 20 weeks Pregnant women with IUGR-based fetal sonography Maternal body mass index between 15 to 30 kg / m² No history of allergies to fish and omega 3 Complete information of patients' files Satisfaction to participate in the study

Intervention groups

The first group will be pregnant mothers who will receive a zinc supplement, the second group will be pregnant mothers who will receive an omega-3 supplement (zinc supplement in the form of tablets containing 30 mg of zinc sulfate produced by Dine Pharmaceutical Company and omega-3 supplement as a Tablets containing EPA eicosapentanoic acid and DHA docosahexaenoic acid produced by Zahravi Pharmaceutical Company

Main outcome variables

neonatal weight ; Apgar score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201130049548N1**

Registration date: **2020-12-19, 1399/09/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-19, 1399/09/29**

Update count: **0**

Registration date

2020-12-19, 1399/09/29

Registrant information

Name

Moona Baboie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3226 1150

Email address

dr.baboie@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-15, 1399/08/25

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of zinc and omega-3 supplementation effect on maternal and fetal outcomes in pregnant women with

IUGR fetus with control group, a double-blind placebo controlled clinical trial study

Public title

Comparison of zinc and omega-3 supplementation effect on maternal and fetal outcomes in pregnant women with IUGR fetus

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women aged 18-35 years Pregnant women with a gestational age of more than 20 weeks Pregnant women with IUGR-based fetal sonography Maternal body mass index between 15 to 30 kg / m² No history of allergies to fish and omega 3 Complete patient information Satisfaction to participate in the study

Exclusion criteria:

Multiple pregnancies Underlying diseases such as diabetes and high blood pressure Existence of structural disorders of the uterus Maternal addiction and smoking Chronic infection (dehydration, fever) Chronic liver and kidney disease placenta previa or decollement

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **117**

Randomization (investigator's opinion)

Randomized

Randomization description

We use the block randomization method to randomize subjects into groups that result in equal sample sizes. We use the block size 6. From the following blocks, first select 1 by accident and divide the samples into three groups according to the order and fill the blocks A for zinc supplementation and B for omega-3 supplementation and C for placebo C C B B A A 1 A C C B B A 2 A A C C B B 3 B A A C C B 4 B B A A C C 5 C A A B B C 6

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind and the medical examiner resident , medication provider and patients would not know about the type of treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Golestan University of Medical Sciences, Gorgan, Shastkola road, Philosophical Higher Education Complex

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2020-11-15, 1399/08/25

Ethics committee reference number

IR.GOUMS.REC.1399.280

Health conditions studied

1

Description of health condition studied

neonatal weight

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Apgar score

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Better neonatal weight gain

Timepoint

Neonatal weight at birth time

Method of measurement

Measuring the weight of a newborn baby with a digital scale

2

Description

Apgar score

Timepoint

5th minute Apgar score

Method of measurement

Based on Apgar scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Zinc supplement recipients (zinc supplement in the form of tablets containing 30 mg of zinc sulfate daily for 6 weeks produced by Dineh Pharmaceutical Company)

Category

Prevention

2

Description

Intervention group: Omega-3 supplement recipients (omega-3 supplement in the form of a tablet containing 180 mg EPA eicosapentaenoic acid and 120 mg docosahexaenoic acid DHA at a dose of 120 mg daily for 6 weeks produced by Zahravi Pharmaceutical Company)

Category

Prevention

3

Description

Control group: Placebo recipients (made by Barij Essential Company daily for 6 weeks)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sayyad Shirazi Hospital

Full name of responsible person

Dr Malihe Azadehrah

Street address

Philosophical Higher Education Complex, Shast Kola Road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3220 2565

Email

m.azadehrah@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Honarvar

Street address

Philosophical Higher Education, Shast Kola Road, Gorgan

City

GorGan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3245 1660

Email

info@goums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Mona Babooui

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Golestan University of Medical Sciences, Shast Kola Road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3220 2565

Email

dr.babooie@goums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mona Babooei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Golestan University of Medical Sciences, Shast Kola Road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3220 2565

Email

dr.babooie@goums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mona Babooei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Golestan University of Medical Sciences, Shast Kola Road, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3220 2565

Email

dr.babooie@goums.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

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