

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Study of the effect of evening primrose oil supplementation on fertility outcomes in the women undergoing IVF treatment: A triple blind randomized controlled trial.

Protocol summary

Study aim

Determining the Effect of Evening Primrose Oil Supplementation on Fertility Outcomes in Infertile Women Treated with IVF

Design

Controlled clinical trial, Phase 3, with two groups of parallel, triple-blind

Settings and conduct

Infertile women referred to Tabriz University of Medical Sciences Infertility Clinic who are candidates for IVF will be stratified based on definition of primary and secondary infertility. The stratification will be based on the proportion of clients (eg 1:1 or 1:2). The envelopes will be uniform, sealed, matte and will be prepared based on the sequence of assignment by the non-involved person. In the first five days of the menstrual IVF cycle, the envelopes No.1 will be given to the first person and this process will continue until the number of samples is completed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with primary and secondary infertility are candidates for IVF, 20-40 years, $18.5 < \text{BMI} < 29.9$ Exclusion criteria: Follow a specific dietary pattern for medical or other reasons, Seizure history, Malignancy, Use of chemotherapy and radiotherapy, Continuous and daily consumption of herbal brews (Borage ...), Tobacco and alcohol or any substance abuse, IVF cycle ≥ 4 , Use donated or frozen sperm or egg, Severe endometriosis, Having uterine anomalies, Use of blood thinners.

Intervention groups

The intervention group will be given 42 capsules of 1000 mg Evening Primrose oil(containing 13% gamma-linolenic acid and 72% linoleic acid) and control group placebo with the same shape and color.

Main outcome variables

Implantation rate, Fertility rate, Fetal quality status,

Pregnancy test status, Side effects of Evening Primrose oil supplementation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110606006709N21**

Registration date: **2020-01-15, 1398/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-15, 1398/10/25**

Update count: **0**

Registration date

2020-01-15, 1398/10/25

Registrant information

Name

Mahnaz Shahnazi

Name of organization / entity

Tabriz University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-07, 1398/09/16

Expected recruitment end date

2020-03-24, 1399/01/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of evening primrose oil supplementation on fertility outcomes in the women undergoing IVF treatment: A triple blind randomized controlled trial.

Public title

The Effect of evening primrose oil on Fertility outcomes in the women undergoing IVF treatment.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with primary and secondary infertility are candidates for IVF Women 20-40 years Women with a BMI between 18.5 and 29.9

Exclusion criteria:

Follow a specific dietary pattern for medical or other reasons History of seizures Malignancy Use of chemotherapy and radiotherapy or history of use corticosteroid drugs for up to one month Continuous and daily consumption of herbal yeas (borage ...) Tobacco and alcohol or any drug abuse IVF cycle ≥ 4 Use of donated sperm or egg or frozen sperm and egg sever endometriosis Having uterine anomalies Use of blood thinners

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned into two groups of recipients of evening primrose oil supplementation and placebo using random blocking method and blocks of size 4 and 6 using Random Allocation Software (RAS) with a 1: 1 assignment ratio by the person not involved in the research. To conceal the allocation, opaque envelopes with sample numbers will be provided and numbered. Preparation of envelopes and sequence generation will be done by a person not involved in the research. In the first five days of the IVF menstrual cycle, envelope No. 1 will be given to the first eligible person, and this process will continue until the number of

samples is completed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the drugs and the placebo will be prepared by the same pharmaceutical company in identical shape, color and smell. participants, researchers, medical staff (doctors, nurses, etc.) who are responsible for patient care, data collection officers and those who evaluate the outcome will not be informed about the drug type.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz Medical Sciences
Biomedical Research

Street address

Faculty of Nursing &Midwifery, South Shariati street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2019-11-21, 1398/08/30

Ethics committee reference number

IR.TBZMED.REC.1398.681

Health conditions studied**1****Description of health condition studied**

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes**1****Description**

Implantation rate

Timepoint

at week 5 of pregnancy will be calculated.

Method of measurement

The implantation rate will be calculated by dividing the

number of sacs visible in the ultrasound by the number of embryos transferred.

2

Description

fertility rate

Timepoint

One day after the IVF procedure will be determined

Method of measurement

Fertility rate It will be calculated as the number of fertilized oocytes divided by the total number of oocytes removed.

Secondary outcomes

1

Description

fetal quality status

Timepoint

On the third day after will be determined fertilization

Method of measurement

Third day, fetal quality under the microscope will be determined by an experienced person according to the fetal quality grading chart.

2

Description

Pregnancy Test Status

Timepoint

14 days after embryo transfer will be determined

Method of measurement

Clinical pregnancy as positive for blood β HCG test will be specified

3

Description

Side Effects evening primrose oil supplementation

Timepoint

During the study will be reported.

Method of measurement

By completing the checklist of side effects will be obtained.

Intervention groups

1

Description

Intervention group: In this study, 1000 mg capsule Evening Primrose oil containing 13% Gamalinolenic acid and 72% Linoleic acid will be prepared by pharmacists of Barij Essence Kashan and 3 capsules daily with food will be used for 2 weeks.

Category

Treatment - Drugs

2

Description

Control group: Passive Capsules, similar in appearance and color to the Primrose oil Capsule, will be prepared by pharmacists of Barij Essence Kashan and 3 capsules daily with food will be used for 2 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra teaching - medical center

Full name of responsible person

Nahid Sohrabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Other areas of specialty/work
Physiology
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Person responsible for general inquiries

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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