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 < 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% gammalinolenic 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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Iran (Islamic Republic of)

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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 βHCG 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% Linileic 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
Mohamad Samiei
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Central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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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
Nahid Sohrabi
Position
Msc Student of Midwifery
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Person responsible for scientific 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