

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of folic acid and folate consumption on ovarian reserve parameters and IVF results in women referred to infertility clinic - a randomized, blinded clinical trial

Protocol summary

Study aim

This study aims to compare the consumption of folic acid and folate on ovarian reserve parameters and IVF results in women referred to infertility clinics.

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, on 280 patients. The block random assignment method was designed by an epidemiologist.

Settings and conduct

280 women suffering from infertility referred to the infertility clinic of Waliast Hospital, where each person is given one pill (folic acid or folate) with the same appearance and daily for 3 months. The patient and the analyst are blinded to the study. In order to hide the random allocation process, the corresponding type of treatment will be written on cardboard cards and placed in identical paper envelopes. The cards will be arranged in the order of the randomization list in a box. For data analysis, a statistician who is separate from the study process and unaware of all the processes will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria - Infertile women aged 30-40 years. (poor response and unknown cause of infertility b. exclusion criteria - Infertility due to PCO; endometriosis; tubal and uterine and having causes of male infertility - History of ovarian or pelvic surgery or medical history of chemotherapy or radiotherapy. - Other medical Diseases - Patients with definite diagnosis of hereditary diseases or family history of hereditary thrombophilic diseases in family or person. History of multivitamin use

Intervention groups

The participants will be randomly assigned to the group of folic acid 1 mg daily (control group) and folate 600 micrograms daily (case group) with the shape and appearance of Bexan for 3 months.

Main outcome variables

Primary: changes in AFC Secondary: changes in FSH, AMH and Inhibin B and side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180409039247N7**

Registration date: **2023-07-31, 1402/05/09**

Registration timing: **prospective**

Last update: **2023-07-31, 1402/05/09**

Update count: **0**

Registration date

2023-07-31, 1402/05/09

Registrant information

Name

Marjan Ghaemibidgoli

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of folic acid and folate consumption on ovarian reserve parameters and IVF results in women referred to infertility clinic - a randomized, blinded clinical trial

Public title
Comparison of folic acid and folate consumption on ovarian reserve parameters and IVF results

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women aged 30-40 with poor response or unknown causes of infertility are candidates for IVF
Exclusion criteria:
Infertility due to PCO; endometriosis; tubal and uterine and having causes of male infertility History of ovarian or pelvic surgery or medical history of chemotherapy or radiotherapy. Diseases associated with viral infections (hepatitis), tumors, autoimmune diseases, endocrine disorders, metabolic disorders or acute inflammation. Patients with definite diagnosis of hereditary diseases or family history of hereditary thrombophilic diseases in family or person. History of multivitamin use

Age
From **30 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **280**

Randomization (investigator's opinion)
Randomized

Randomization description
participants will be randomly assigned to folic acid and folate groups. A computerized randomization list, generated by an independent statistician blinded to the trial and unrelated to the subjects involved, will use 1:1 allocation. All participants are blinded to the list. The randomization list will be administered using identical, sequentially numbered study drug containers, and these containers will be identically labeled by two investigators who will not be involved in the recruitment of study subjects. The block random allocation method was designed by an epidemiologist using WWW.Sealedenvelop.com. The blocks will be 2 alleles of size 6. AAABBB-AABBAB-ABBBAA-AABABB-....., in this sequence, A is folic acid and B is folate.

Blinding (investigator's opinion)
Single blinded

Blinding description
The list of random allocation of patients will only be at the disposal of the project epidemiologist. In order to hide the random allocation process, the relevant type of treatment will be written on cardboard cards and placed in paper envelopes of the same shape. Only the project methodologist will be aware of the contents of the envelopes. The cards will be arranged in the order of the randomization list inside the box. When the doctor declares the eligibility of a patient, the methodologist will provide the envelope design to the therapist. The person evaluating the intended outcomes is a third person who is unaware of the randomization process and the type of treatment performed. In order to analyze the data, a statistician who is separate from the study process and is unaware of all the processes will be used. It should be noted that the medicines of one form are provided by the pharmaceutical company to the project manager to be prescribed to the patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university of medical sciences

Street address

East Bagherkhan Street, Imam Complex

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Province

Tehran

Postal code

13245

Approval date

2023-07-19, 1402/04/28

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.165

Health conditions studied

1

Description of health condition studied

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Primary outcome: changes in the number of antral follicles. Secondary outcome: changes in FSH, AMH and Inhibin B and checking the level of possible side effects

Timepoint

The results will be evaluated at the beginning of the study and after three months from the start of the study.

Method of measurement

To check AFC vaginal ultrasound and to measure FSH, AMH and Inhibin laboratory (blood sample) will be used.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: oral folate tablets 600 micrograms daily

Category

Treatment - Drugs

2

Description

Control group: 1 mg oral folic acid tablet

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali e Asr Hospital

Full name of responsible person

Marjan Ghaemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Marjan Ghaemi

Position

Assistant professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

here is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available