Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Waliasr 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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Iran (Islamic Republic of)

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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

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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
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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