Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of the effect of folate supplementation compared with the placebo on treatment and metabolic profiles in patients with endometrial hyperplasia

Protocol summary

Summary

Objective: The aim of this study is to determine the effects of folate supplementation on treatment and metabolic profiles including insulin resistance and inflammatory factors in patients with endometrial hyperplasia. Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers. Inclusion criteria: Patients with endometrial hyperplasia and aged 30 to 50 years will be included in this study. Exclusion criteria: Unwillingness to cooperate will be excluded in the study. Population and sample size: 60 patients with endometrial hyperplasia of eligible and referred to Kosar Clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected. Intervention: Patients will be assigned to receive either folate (n=30) or placebo (n=30). Folate and placebos capsules are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and end of the intervention: 12 weeks. Outcomes: Response to treatment (primary outcomes), and insulin metabolism parameters and inflammatory factors (secondry outcomes) will be quantified at the study baseline and end-of-trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201704155623N107**
Registration date: **2017-05-12, 1396/02/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-12, 1396/02/22

Registrant information

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Kashan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of folate supplementation compared with the placebo on treatment and metabolic profiles in patients with endometrial hyperplasia

Public title

Effect of supplementation in treatment of patients with endometrial hyperplasia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with endometrial hyperplasia; aged 30 to 50 years. Exclusion criteria: Unwillingness to cooperate.

Age

From **30 years** old to **50 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak

City

Arak

Postal code

Approval date

2016-04-11, 1395/01/23

Ethics committee reference number

IR.ARAKMU.REC.1394.336

Health conditions studied

1

Description of health condition studied

Endometrial hyperplasia

ICD-10 code

E11.2

ICD-10 code description

Endometrial hyperplasia

Primary outcomes

1

Description

Response to treatment

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Biopsy

Secondary outcomes

1

Description

Hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

2

Description

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

4

Description

Fasting plasma glucose

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: 5 mg folate (Tehran Darou, Tehran, Iran), daily, for 12 weeks orally.

Category

Treatment - Drugs

2

Description
Control group: Placebo (Barij Essence, Kashan, Iran), daily, for 12 weeks orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Clinic
Full name of responsible person
Mehri Jamilian
Street address
Emam Khomeyni Avenue, Arak
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Mohammad Rafiee
Street address
Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Email
asemi_z@kaums.ac.ir; asemi_r@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty