Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Study aim

The aim of this study is to determine the effects of vitamin D supplementation on treatment and metabolic profiles including insulin resistance and lipid profiles in patients with endometrial hyperplasia.

Design

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.

Settings and conduct

Population and sample size: 60 patients with endometrial hyperplasia of eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with endometrial hyperplasia and aged 35–55 years old will be included in this study. Exclusion criteria: Menopausal women, history of cardiovascular disease, diabetes mellitus, fasting plasma glucose (FPG) > 126 mg/dL, consumption of antihyperglycemic agents including metformin, triglycerides levels > 500 mg/dL, systolic blood pressure ≥ 160 mmHg, diastolic blood pressure ≥ 110 mmHg and untreated thyroid disease

Intervention groups

Intervention: Patients will be assigned to receive either vitamin D (n=30) or placebo (n=30). Vitamin D and placebos capsules are similar in shape and size.

Main outcome variables

Outcomes: Response to treatment (primary outcomes), and insulin metabolism parameters, lipid and metabolic profiles (secondry outcomes) will be quantified at the study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201606275623N86**
Registration date: **2016-07-01, 1395/04/11**
Registration timing: **retrospective**

Last update: **2019-09-22, 1398/06/31**
Update count: **1**

Registration date

2016-07-01, 1395/04/11

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2016-05-25, 1395/03/05

Expected recruitment end date

2016-06-24, 1395/04/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of vitamin D 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:

Aged 35 to 55 years Patients with endometrial hyperplasia informed consent

Exclusion criteria:

Menopausal women History of cardiovascular disease Diabetes mellitus Fasting plasma glucose (FPG) > 126 mg/dL Consumption of antihyperglycemic agents including metformin Triglycerides levels > 500 mg/dL Systolic blood pressure ≥ 160 mmHg Diastolic blood pressure ≥ 110 mmHg Untreated thyroid disease

Age

From **35 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take vitamin D supplementation (n=30) or placebo (n=30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

1771844351

Approval date

2016-05-24, 1395/03/04

Ethics committee reference number

IR.Kaums.REC.1395.19

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

Sonography

Secondary outcomes

1

Description

Insulin

Timepoint

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

Method of measurement

Elisa kit

2

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

Cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

HDL

Timepoint

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

Method of measurement

Enzymatic kit

5

Description

Total antioxidant

Timepoint

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

Method of measurement

Spectrophotometry

6

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

7

Description

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

8

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

9

Description

Insulin resistance

Timepoint

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

Method of measurement

Using HOMA formula

10

Description

VLDL cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: 50000 IU vitamin D (Zahravi, Tabriz, Iran), once a week, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Barij Essence, Kashan, Iran), once a week, for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Naghavi Clinic

Full name of responsible person

Zatollah Asemi

Street address

Shahid Rajaee Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
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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
Vice chancellor for research, Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Web page address

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