Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial of the effect of folate supplementation compared with the placebo on recurrence and metabolic profiles in women with cervical intraepithelial neoplasia 2 and 3

Protocol summary

Summary

Objective: The aim of this study is to determine the effects of folate supplementation on recurrence and metabolic profiles in women with cervical intraepithelial neoplasia 2 and 3. Study design: Parallel double-blind (both participants and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers. Inclusion criteria: Women with cervical intraepithelial neoplasia 2 and 3, and aged 18 to 55 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 cervical intraepithelial neoplasia 2 and 3 of eligible and referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected. Intervention: Participants will be assigned to receive either folate supplements (intervention group: n=30) and placebo (control group: n=30). Fasting blood samples will be taken at baseline and after 3-mo intervention. Start and end date of intervention: 3 months. Outcomes: Metabolic profiles will be meseaured at study baseline and end-of-trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021417639N2**
Registration date: **2017-02-27, 1395/12/09**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2017-02-27, 1395/12/09

Registrant information

Name
MOJGAN NOURIAN
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 3792 2671
Email address
nourian@hlth.mui.ac.ir

Recruitment status

Not enough for processing

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2017-01-22, 1395/11/03

Expected recruitment end date

2016-03-22, 1395/01/03

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 recurrence and metabolic profiles in women with cervical intraepithelial neoplasia 2 and 3

Public title

Effect of supplementation in treatment of women with cervical intraepithelial neoplasia 2 and 3

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: women with cervical intraepithelial neoplasia 2 and 3; aged 18 to 55 years old. Exclusion criterion: unwillingness to cooperate.
Age
From **18 years** old to **55 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 Isfahan University of Medical Sciences
Street address
Building No. 4, Hezar Jerib Avenue, Isfahan University of Medical Science, Isfahan
City
Isfahan
Postal code
Approval date
2017-01-22, 1395/11/03
Ethics committee reference number
IR.MUI.REC.1395.3.733

Health conditions studied

1

Description of health condition studied
Cervical intraepithelial neoplasia 2 and 3
ICD-10 code
C53.9
ICD-10 code description
Cervix uteri, unspecified

Primary outcomes

1

Description
Recurrence
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Colposcopy

Secondary outcomes

1

Description
Fasting plasma glucose
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

2

Description
Hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

3

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

4

Description
Total antioxidant
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

5

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

6

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

7

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

8

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

9

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

10

Description
Insulin
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

Intervention groups

1

Description
Intervention group: Folate supplement, 5 mg, daily, for 12 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo tablet, daily 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
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Science
Full name of responsible person
Amir Mansoor Alavi
Street address
Building No. 4, Hezar Jerib Avenue, Isfahan University of Medical Science, Isfahan
City
Isfahan
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, Isfahan University of Medical Science
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
Isfahan University of Medical Science/Nutrition Department
Full name of responsible person
Mojgan Nourian
Position

Ph.D / Lecturer

Other areas of specialty/work

Street address

Nutrition Department, Hezar Jerib Avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code

Phone

+98 31 3792 2671

Fax

Email

nourian@hlth.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Science

Full name of responsible person

Mojgan Nourian

Position

PhD/lecture

Other areas of specialty/work

Street address

Nutrition Department, Hezar Jerib Avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code

Phone

+98 31 3792 2671

Fax

Email

nourian@hlth.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of Nutrition and Food Sciences

Full name of responsible person

Mojgan Nourian

Position

Ph.D/ Lecture

Other areas of specialty/work

Street address

Nutrition Department, Hezar Jerib Avenue, Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Postal code

Phone

00

Fax

Email

nourian@hlth.mui.ac.ir

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