

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 measured 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**

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**Full name of responsible person**

Mojgan Nourian

**Position**

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**Other areas of specialty/work**

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**Phone**

00

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**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*