

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The effect of folate supplementation on treatment, metabolic profiles and hs-CRP in women with cervical intraepithelial neoplasia 1(CIN1)

#### Protocol summary

##### Study aim

Objective: The aim of this study is to determine the effects of folic acid supplementation on treatment, metabolic profiles and hs-CRP in women with cervical intraepithelial neoplasia 1(CIN1).

##### Design

In this randomized double-blind placebo-controlled trial, patients will be assigned into two groups to receive folate supplements or placebo.

##### Settings and conduct

Fifty eight women with CIN1 eligible and referred to Oncology Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

##### Participants/Inclusion and exclusion criteria

Patients aged between 18 and 55 years with CIN1 will be included. The exclusion criteria will be as follows: women who had a history of cervical cancer or other cancers of the lower genital tract, a history of hysterectomy or destructive therapy of the cervix and pregnant women.

##### Intervention groups

Patients will be assigned to receive either 5 mg folate supplement (intervention group: n=29) or placebo (control group: n=29).

##### Main outcome variables

Fasting plasma glucose (FPG), serum insulin, lipid profiles and hs-CRP levels.

#### General information

##### Reason for update

Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were in accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201403155623N17**

Registration date: **2014-03-25, 1393/01/05**

Registration timing: **retrospective**

Last update: **2019-11-04, 1398/08/13**

Update count: **1**

##### Registration date

2014-03-25, 1393/01/05

##### 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

Kashan University of Medical Sciences

##### Expected recruitment start date

2013-09-27, 1392/07/05

##### Expected recruitment end date

2014-01-03, 1392/10/13

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of folate supplementation on treatment, metabolic profiles and hs-CRP in women with cervical intraepithelial neoplasia 1(CIN1)

##### Public title

Effect of supplementation in treatment of cervical intraepithelial neoplasia 1

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Women aged 18-55 years Diagnosed with cervical intraepithelial neoplasia 1

#### **Exclusion criteria:**

Women who had a history of cervical cancer or other cancers of the lower genital tract History of hysterectomy or destructive therapy of the cervix Pregnant women

### **Age**

From **18 years** old to **55 years** old

### **Gender**

Female

### **Phase**

2-3

### **Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

### **Sample size**

Target sample size: **58**

### **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 either folate supplements (n = 29) or placebo (n = 29). Randomization will be done by the use of computer-generated random numbers.

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Oncology Clinic at the Kashan University of Medical Sciences, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Kashan University of Medical Sciences

### **Street address**

Ghotbe Ravandi blvd, Kashan

### **City**

Kashan

### **Province**

Isfahan

### **Postal code**

8115187159

### **Approval date**

2010-09-23, 1389/07/01

### **Ethics committee reference number**

5008/1/5/29/P

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Cervical intraepithelial neoplasia 1(CIN1)

#### **ICD-10 code**

C53.9

#### **ICD-10 code description**

Cervix uteri, unspecified

## **Primary outcomes**

### 1

#### **Description**

Cervical intraepithelial neoplasia grade

#### **Timepoint**

Baseline and End-of-trial

#### **Method of measurement**

Colposcopy

## **Secondary outcomes**

### 1

#### **Description**

Insulin

#### **Timepoint**

Baseline and End-of-trial

#### **Method of measurement**

Elisa kit

### 2

#### **Description**

Insulin resistance

#### **Timepoint**

Baseline and End-of-trial

#### **Method of measurement**

Calculation using HOMA formula

### 3

#### **Description**

Total cholesterol

#### **Timepoint**

Baseline and End-of-trial

#### **Method of measurement**

Enzymatic kit

#### 4

**Description**

Triglycerides

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Enzymatic kit

#### 5

**Description**

HDL

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Enzymatic kit

#### 6

**Description**

High-sensitivity C-reactive Protein

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Elisa kit

#### 7

**Description**

Nitric oxide

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Spectrophotometry

#### 8

**Description**

Glutathione

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Spectrophotometry

#### 9

**Description**

Total antioxidant capacity

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Spectrophotometry

#### 10

**Description**

Malondialdehyde

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Spectrophotometry

#### 11

**Description**

Fasting blood sugar

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Enzymatic kit

#### 12

**Description**

Hcy

**Timepoint**

Baseline and End-of-trial

**Method of measurement**

Enzymatic kit

### Intervention groups

#### 1

**Description**

Intervention group: Folic acid tablet, 5 mg, daily, for 6 months orally.

**Category**

Treatment - Drugs

#### 2

**Description**

Control group: Placebo tablet, daily, for 6 months orally.

**Category**

Treatment - Drugs

### Recruitment centers

#### 1

**Recruitment center**

**Name of recruitment center**

Naghavi Oncology Clinic

**Full name of responsible person**

Zatollah Asemi

**Street address**

Shahid Rajaei Avenue, Kashan

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**Phone**

+98 31 5546 3378

**Email**

asemi\_r@yahoo.com

### Sponsors / Funding sources

#### 1

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zatollah Asemi

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Bolvare Ghotbe Ravandi, Kashan

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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**

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**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Full name of responsible person**

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**Position**

Nutrition PhD

**Latest degree**

Ph.D.

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Zatollah Asemi

**Position**

Nutrition PhD

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Phone**

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**Fax****Email**

asemi\_r@yahoo.com

**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