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 CIN1will 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

Isfehan

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 Rajaee Avenue, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
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
Street address
Bolvare Ghotbe Ravandi, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
Email
asemi_r@yahoo.com

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
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
Email
asemi_r@yahoo.com

Person responsible for scientific inquiries

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
Street address
کاشان، بلوار قطب راوندی
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
Fax
Email
asemi_r@yahoo.com
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
Street address
Bolvare Ghotbe Ravandi, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
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