

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Cytopathologic and Colposcopic findings evaluation of supplementation therapy on cervix precancerous lesion

Protocol summary

Summary

Study propose: the effect of multivitamin on cervix precancerous lesion. Study design: RCT (double blind). Study Population: 120 patients with abnormal pop smear (ASCUS, ASC-H,LSIL) and related clinical symptoms and signs at Fatemiyeh hospital. Inclusion criteria: Cervical intraepithelial Neoplasia (CIN1); Atypical cell with HPV positive. Exclusion criteria: CIN2 or more in primary pathology report after biopsy. Intervention: mineral and multivitamin and 30 mg per day Q10 during 3 mounts and plasebo for control group. Outcome: disappear of lesion in CIN1 level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102719694N1**
Registration date: **2015-05-10, 1394/02/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-10, 1394/02/20

Registrant information

Name

Azar Pirdehghan

Name of organization / entity

Hamadan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamadan University of Medical Sciences

Expected recruitment start date

2015-02-17, 1393/11/28

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cytopathologic and Colposcopic findings evaluation of supplementation therapy on cervix precancerous lesion

Public title

The effect of multivitamine on precancerous leision of cervix

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Cervical intraepithelial Neoplasia (CIN1); Atypical cell with HPV positive. Exclusion criteria: CIN2 or more in primary pathology report after biopsy.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

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**

Hamadan university of medical sciences ethical committee

Street address

Ethical committee, Medical school, Hamadan University of medical sciences, Hamadan, Iran.

City

Hamadan

Postal code**Approval date**

2015-03-02, 1393/12/11

Ethics committee reference number

6367/9/35/16پ

Health conditions studied**1****Description of health condition studied**

Cervix cancer

ICD-10 code

C53

ICD-10 code description

Malignant neoplasm of cervix uteri

Primary outcomes**1****Description**

Cure of Cin1 lesion

Timepoint

Pre intervention, 6 months after trial

Method of measurement

Pathology report

Secondary outcomes

empty

Intervention groups**1****Description**

Mineral and multivitamin and 30 mg per day Q10 during 3 mounts in intervention group

Category

Treatment - Drugs

2**Description**

control group: plasebo

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Fatemiyeh Hospital

Full name of responsible person

Mehrangiz Zamani

Street address

Fatemiyeh Hospital, Kermanshah street, Hamadan, Iran.

City

Hamadan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Hamadan university of medical sciences

Full name of responsible person

Saeed Bashirian

Street address

Vice chancellor for research, Hamadan University of medical sciences, Hamadan, Iran.

City

Hamadan

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, Hamadan university of medical sciences

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**

Hamadan university of medical sciences

Full name of responsible person

Danial Farhadi

Position

Medical student

Other areas of specialty/work**Street address**

Community medicine department, Medical school,
Hamadan University of medical sciences, Hamadan,
Iran.

City

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hamadan university of medical sciences

Full name of responsible person

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Position

Community medicine assistant proffessor

Other areas of specialty/work**Street address**

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Web page address**Person responsible for updating data****Contact****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