

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jun 2026

### Efficiency of oral zinc sulphate supplement on clearance of cervical human papilloma virus

#### Protocol summary

clearance of cervical human papilloma virus

#### Study aim

To assess the effect of oral zinc sulphate in clearance of cervical human papilloma virus (HPV). To assess the effect of oral zinc sulphate in clearance of cervical human papilloma virus (HPV) and age. To assess the effect of oral zinc sulphate in clearance of cervical human papilloma virus (HPV) and OCP. To assess the effect of oral zinc sulphate in clearance of cervical human papilloma virus (HPV) and smoking.

#### Design

Clinical trials with control group, non-randomised with blinded postoperative care and outcome assessment.

#### Settings and conduct

Gynecology clinic of Motahari Hospital.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria are the following: having a positive HPV DNA test and Pap smear cytology report of either ACUS or LSIL. Patients with abnormal serum zinc level, ongoing pregnancy, breast feeding, immune compromised state diagnosis and prior history of cone biopsy were excluded from study. Exclusion criteria are the following: having a positive HPV DNA test and Pap smear cytology report of either ACUS or LSIL. Patients with abnormal serum zinc level, ongoing pregnancy, breast feeding, immune compromised state diagnosis and prior history of cone biopsy were excluded from study.

#### Intervention groups

According to previous studies, based on the fact that zinc has a strengthening effect on the immune system, in some studies it has caused viral clearance and wart healing. In our study, patients who have an abnormal Pap smear or a positive viral genome and their serum levels are normal will be given oral zinc sulfate capsules and will have another Pap smear and viral genome re-examined three months later. We will not have therapeutic intervention in the control group and will be re-examined and compared with the intervention group three months later.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210407050882N1**

Registration date: **2021-04-15, 1400/01/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-04-15, 1400/01/26**

Update count: **0**

##### Registration date

2021-04-15, 1400/01/26

##### Registrant information

##### Name

Naghme Zandvakili

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3366 4468

##### Email address

zandvakilinaghme@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-09, 1400/01/20

##### Expected recruitment end date

2021-06-21, 1400/03/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Efficiency of oral zinc sulphate supplement on clearance of cervical human papilloma virus

### Public title

Effect of zinc sulphate in papilloma virus

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

positive HPV DNA test LSIL in pap smear Ascus in pap smear

#### Exclusion criteria:

Pregnancy Breast feeding Immunocompromised state deasie Perior history of cervical cone biopsy or LEEP

### Age

From **21 years** old to **55 years** old

### Gender

Female

### Phase

1-2

### Groups that have been masked

- Investigator

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Not randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Tha research is blind and given oral zinc sulphate tables by the clinical caregiver on even days,and the individual day patients place in the control group.

### Placebo

Not used

### Assignment

Other

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Urmia University of medical sciences

##### Street address

Urmia, Emergency Ave , Resalat Blvd

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

3457871437

### Approval date

2018-12-12, 1397/09/21

### Ethics committee reference number

IR.UMSU.REC.1397.366

## Health conditions studied

### 1

#### Description of health condition studied

Abnormal papsmear and cervical cytology

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Effect of oral zinc sulphat(in department variable)in clearance of cervical human papilloma virus (dependent variable)

#### Timepoint

Both groups check their serum zinc levels at start and the end of study,which is before the star of zinc supplement and 30 days after the last dose of zinc for intervention group.Than in both groups do pap smear and cervical HPV typing.

#### Method of measurement

Repeat pap smear and HPV typing in same laborator

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group:no medication

#### Category

Other

### 2

#### Description

Intervention group: Before starting the study, the subject of research on the relationship between serum zinc levels and the possibility of purification of cervical human papilloma virus and effect and probably side effects of zinc sulphate supplement explain to all patients and with knowledge and cosent enter the study.Than given zinc sulphate capsule 220 mg (zinc 50 mg) twice a day for three months.cap zinc sulphate 220 mg 7H2O made in iran.

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shahid motahari hospital

**Full name of responsible person**

Naghme zandvakili

**Street address**

No .1, kashani Ave

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

1546357146

**Phone**

+98 44 2223 2007

**Email**

Zandvakilinaghme@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Zahra Yekta

**Street address**

No.1 ,Khashani Ave

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

6417536451

**Phone**

+98 44 2223 2007

**Email**

zandvakilinaghme@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Oroumia 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**

Oroumia University of Medical Sciences

**Full name of responsible person**

Naghme zandvakili

**Position**

Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

No.44 , modiriat Ave

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5719177616

**Phone**

+98 44 3366 4468

**Email**

zandvakilinaghme@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Hale Ayatollahi

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

No,7. Daneshkade Ave

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5719177619

**Phone**

+98 44 3357 2631

**Email**

elham.rjb68@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Elham rajabi

**Position**

Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

No.1, Roudaki Ave

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5719177616

**Phone**

+98 44 3366 4468

**Email**

elham.rjb68@gmail.com

**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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available