

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Efficacy and safety of cryotherapy in comparison with Chinese herbal medicine in the treatment of chronic cervicitis and cervical erosion

Protocol summary

Summary

Objectives: Comparing the effectiveness and safety of cryotherapy in comparison with Chinese herbal medicine in the treatment of chronic cervicitis and cervical erosion. Design: randomized Controlled Trial. Setting and conduct: 70 patients with chronic cervicitis or cervical erosion referred to gynecology clinic of Imam Reza and Ghaem hospitals will be entered to the study. All subjects will be evaluated for study outcomes at 48 hours after treatment, week 1, 3 days after the end of menstruation, weeks 6 and 12. Major Inclusion and Exclusion criteria: Cervicovaginal smears class 1 or 2; no report of papilloma or CIN). Intervention: herbal treatment (experimental) and cryotherapy (control). Main outcome measures: the cervicitis degree, side effects, complications and recurrence rate and the time of recovery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512107265N4**

Registration date: **2016-06-14, 1395/03/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-14, 1395/03/25

Registrant information

Name

Hoda Azizi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1855 2188

Email address

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Recruitment status

Recruitment complete

Funding source

Deputy of Research of Mashhad University of Medical Sciences

Expected recruitment start date

2015-12-19, 1394/09/28

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of cryotherapy in comparison with Chinese herbal medicine in the treatment of chronic cervicitis and cervical erosion

Public title

Efficacy and safety of cryotherapy in comparison with Chinese herbal medicine in the treatment of chronic cervicitis and cervical erosion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Developing chronic cervicitis or cervical erosion; Papanicolaou smear class 1 or 2; Normal colposcopy. Exclusion criteria: Papanicolaou smear indicating papilloma or CIN; Sensitivity to plastic materials; Cervical prolapse greater than grade 1

Age

From **12 years** old to **60 years** old

Gender

Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 70

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Subjects will be randomly assigned to study groups using a random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

MUM's central office, Daneshgah street, Mashhad

City

Mashhad

Postal code

Approval date

2012-03-14, 1390/12/24

Ethics committee reference number

900410

Health conditions studied

1

Description of health condition studied

Chronic cervicitis

ICD-10 code

N72

ICD-10 code description

Inflammatory disease of cervix uteri

Primary outcomes

1

Description

the degree of cervicitis

Timepoint

Before intervention, 48 hours after the intervention, one

week after the intervention, 3 days after the end of the next menstruation and at weeks 6 and 12

Method of measurement

clinical examination of cervix (observation) and recording in the study check list

Secondary outcomes

1

Description

complications

Timepoint

48 hours after the intervention, one week after the intervention, 3 days after the end of the next menstruation and at weeks 6 and 12

Method of measurement

questionnaire

2

Description

Time to treatment response

Timepoint

Before intervention, 48 hours after the intervention, one week after the intervention, 3 days after the end of the next menstruation and at weeks 6 and 12

Method of measurement

clinical examination of cervix (observation) and recording in the study check list

Intervention groups

1

Description

Intervention group: Cervicitis Treatment Tray which is a patent made by Beijing Jinyongyuan Medical applianceco. It mainly contains Cortex Phellodendri. The herbal formulation is placed on a plastic tray which is geometrically compatible with cervix. The tray is passed through the vaginal speculum and to be put on the cervix and removed 24 to 48 hours later.

Category

Treatment - Drugs

2

Description

Control group: cryotherapy

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology Clinic of Imam Reza Hospital

Full name of responsible person

Dr. Nayereh Khadem

Street address

Gynecology Clinic, Imam Reza Hospital, Ibn Sina Street

City

Mashhad

2**Recruitment center****Name of recruitment center**

Gynecology Clinic of Ghaem Hospital

Full name of responsible person

Dr. Malihe hasanzade

Street address

Gynecology Clinic, Ghaem Hospital, Ahmadabad Street

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

MUM's central office, Daneshgah street

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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

Mashhad 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**

Department of Chinese and Complementary Medicine

Full name of responsible person

Dr Hoda Azizi

Position

MD, PhD in Acupuncture, Assistant Professor

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

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

Gynecology Research Center

Full name of responsible person

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Position

Gynecologist, Associate professor

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Mashhad University of Medical Sciences

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Position

Assistant Professor

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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