Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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 spaculum 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
City
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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
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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
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Person responsible for scientific inquiries

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Gynecology Research Center
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Person responsible for updating data

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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