Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Combined pharmaco and Cryotherapy compared with only pharmacotherapy in symptomatic chronic cervicitis

Protocol summary

Summary

Objective: The main aim is "Combined pharmaco and cryotherapy compared with only pharmacotherapy in symptomatic chronic cervicitis". The more effective and quick treatment of chronic cervicitis in women, prevention of their referral to physicians, promotion of life quality decline of cure costs are the other aims. Design: Study population are 120 persons in both control and intervention groups that have been chosen from referred women of Mobini hospital - clinic. Setting and conduct: This double blind clinical trial study is performed in women with symptomatic cervical ectopy. At the first through an interview, demographic data, the duration and symptoms of the disease is recorded on a checklist and then Pap-smear is prepared totally. The fitted women are divided into control and intervention groups. Inclusion criteria: These criteria are including cervical ectopy, the age between 15-55, married, and symptoms of chronic cervicitis such as pain during intercourse, spotting, vaginal itching and pruritus, hypogastric pain and increasing vaginal discharge. Exclusion criteria are pap-smear class 3 or more vaginal candidiasis and menopause. Intervention: In both groups drug (Metronidazol) is prescribed. A trained midwife performs cryotherapy in intervention group and cryo-placebo in control group. Outcome: The main outcome is improvement of vaginal discharge which is evaluated before, one and three months after treatment and recorded in the checklist. They are re-visited by the physician.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101719559N1**
Registration date: **2015-03-16, 1393/12/25**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-03-16, 1393/12/25

Registrant information

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Name of organization / entity
Sabzevar University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2014-10-27, 1393/08/05

Expected recruitment end date

2014-12-24, 1393/10/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Combined pharmaco and Cryotherapy compared with only pharmacotherapy in symptomatic chronic cervicitis

Public title

Efficacy of freeze in treatment of cervical erosion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: Married, Symptoms of chronic cervicitis including: Increase of vaginal discharge, pain during intercourse, vaginal itching and pruritus, age between 15-55 years old Exclusion: Acute vaginal candidiasis, menopause

Age
From **15 years** old to **55 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **130**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The randomization is performed by the random number table. Blinding is performed as the trained midwife uses Cryo-therapy and Cryo-placebo by accidental allocation. Whereas the researchers , participants and analysts are unaware of the kind of intervention for each person. Although pharmacotherapy is the same for both groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Sabzevar University of Medical Sciences

Street address
Central organization of Sabzevar University of Medical Sciences, Asadabadi St., Sabzevar

City
Sabzevar

Postal code
9613873137

Approval date
2014-05-12, 1393/02/22

Ethics committee reference number
Medsab.Rec.93.3

Health conditions studied

1

Description of health condition studied
Symptomatic chronic cervicitis

ICD-10 code
N72

ICD-10 code description
Endocervicitis with or without erosion or ectropion

Primary outcomes

1

Description
Vaginal discharge

Timepoint
One and three months after treatment

Method of measurement
Check list

Secondary outcomes

1

Description
vaginal itching and pruritus

Timepoint
1 and 3 months after treatment

Method of measurement
Check list

2

Description
Dyspareunia

Timepoint
1 and 3 months after treatment

Method of measurement
Check list

Intervention groups

1

Description
Intervention: Metronidazol(Alborz Darou pharmaceutical Co.)500 mg given orally twice a day until 10 days. Also cryotherapy in cervix was done with N2o(C 501, EMD Co; Tehran, Iran) until forming ice ball in position for every patient.

Category
Other

2

Description
Control: Metronidazol(Alborz Darou pharmaceutical Co.)500 mg given orally twice a day until 10 days.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mobini hospital of Sabzevar
Full name of responsible person
Jila Agah
Street address
Mobini hospital, Kashefi St., Sabzevar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Sabzevar University of Medical Sciences
Full name of responsible person
Mohammad Mohammadzadeh
Street address
Vice chancellor for research, Sabzevar University of Medical Sciences, next Way Police, Sabzevar
City
Sabzevar
Grant name
Grant code / Reference number
393010204
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Sabzevar 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
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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