Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the therapeutic effect of cervix cryotherapy with and without nobothian cyst drainage in the treatment of women with chronic cervicitis

Protocol summary

Summary

This study is designed for investigation the therapeutic effect of cryotherapy with and without nobothian cyst drainage in 144 women with chronic cervicitis. Patients are married women who have children with out history of immune deficiency diseases and cancers especially genitalia ones. Pap smear and culture will be taken from patients to rule out CIN(cervical intraepithelial neoplasm). If pap smears and cultures are normal, treatment will be started. Patients are divided in to two groups, each one included 72 women randomly. In one group cryotherapy will be done after nobothian cyst drainage and in the other group cryotherapy will be done without nobothian cyst drainage. Patients will be examined once a months for investigating therapeutic effects like abdominal pain, dysuria, frequency, dyspareunia, vaginal discharge and bleeding after intercourse for three months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022821653N4**
Registration date: **2017-03-10, 1395/12/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-03-10, 1395/12/20

Registrant information

Name

Athar Rasekh Jahromi

Name of organization / entity

Jahrom University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 5432 6602

Email address

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Recruitment status

Recruitment complete

Funding source

Jahrom University of Medical Sciences

Expected recruitment start date

2015-06-25, 1394/04/04

Expected recruitment end date

2016-06-24, 1395/04/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the therapeutic effect of cervix cryotherapy with and without nobothian cyst drainage in the treatment of women with chronic cervicitis

Public title

Comparing the therapeutic effect of cervix cryotherapy with and without nobothian cyst drainage in the treatment of women with chronic cervicitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included a married woman who has a child and enters the study after knowing all aspects of the study with satisfaction. Exclusion criteria included the presence of certain immune deficiency diseases, especially cancers of the reproductive system and non-

existence of the patient satisfaction for entering the study.

Age
From **20 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Motahari boulevard, Jahrom University of Medical Sciences, Jahrom

City
Jahrom

Postal code

Approval date
2016-01-30, 1394/11/10

Ethics committee reference number
IR.JUMS.REC.1394.163

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
Hypogastric pain

Timepoint
Visiting the patient once a month for three months after intervention

Method of measurement
check list, patients expression

2

Description
Dysuria

Timepoint
Visiting the patient once a month for three months after intervention

Method of measurement
check list, patients expression

3

Description
Dyspareunia

Timepoint
Visiting the patient once a month for three months after intervention

Method of measurement
check list, patients expression

4

Description
green or yellow vaginal discharge

Timepoint
Visiting the patient once a month for three months after intervention

Method of measurement
check list, vaginal examination

5

Description
bleeding after intercourse

Timepoint
Visiting the patient once a month for three months after intervention

Method of measurement
check list, patients expression

6

Description
Mucopurulent vaginal discharge

Timepoint
Visiting the patient once a month for three months after intervention

Method of measurement
check list, vaginal examination

Secondary outcomes

1

Description
cervix stenosis
Timepoint
once a month for three months
Method of measurement
check list, vaginal examination

2

Description
uterus adhesion
Timepoint
visting the pateint once a month for three months
Method of measurement
check list, sonography

3

Description
uterus prolapse
Timepoint
visting the pateint once a month for three months
Method of measurement
check list, vaginal examination

4

Description
spotting
Timepoint
visting the pateint once a month for three months
Method of measurement
check list, patients expression

5

Description
hypogastric pain
Timepoint
visting the pateint once a month for three months
Method of measurement
check list, patients expression

6

Description
infertility
Timepoint
once a month for three months
Method of measurement
check list, patients follow up

7

Description
idiopathic abortion
Timepoint
visting the pateint once a month for three months
Method of measurement
check list, patients follow up

8

Description
making a mistake in diagnosis with ectropion or tissue damage
Timepoint
visting the pateint once a month for three months
Method of measurement
check list, patients follow up

Intervention groups

1

Description
Interventional group one, cryotherapy without nabothian cyst drainage
Category
Treatment - Surgery

2

Description
Interventional group two, cryotherapy is done after nobothian cyst drainage with needle 5 cc in controlled and healthy procedure
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Peymanieyeh clinic related to Jahrom University of Medical Sience
Full name of responsible person
Doctor Athar Rasekh Jahromi
Street address
Peymanieyeh chinic, Peymanieyeh street, Jahrom
City
Jahrom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Jahrom University of Medical Sience
Full name of responsible person
Doctor Kavous Solhjo
Street address
Jahrom University of Medical Sience, Motahari boluvar, Jahrom
City
Jahrom
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, Jahrom University of Medical Sience
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
Jahrom University of Medical Sience
Full name of responsible person
Doctor kavous Solhjo
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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