

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A clinical study of efficacy of garlic extract versus cryotherapy in the treatment of genital wart

Protocol summary

Study aim

Comparison of the effect of garlic extract with cryotherapy in the treatment of female genital warts

Design

This study is a phase 3 clinical trial to compare garlic extract and cryotherapy in the treatment of female genital warts. The total sample size will be 100 people who will be randomly assigned in two groups of 50 people in parallel with the Rand function of Excel software.

Settings and conduct

In this clinical trial, women with genital warts referred to Fatemeh Hospital in Hamadan who have no history of previous treatment and no underlying diseases, if they agree to participate in the study, will be randomly assigned to two groups of garlic extract and cryotherapy. Both groups will be evaluated every 15 days for degree of improvement and possible side effects. Due to the nature of the study, blinding will not be performed.

Participants/Inclusion and exclusion criteria

Participants will be women with vaginal genital warts who had not been treated for the past 6 months. patients with underlying diabetes, high blood pressure, ischemic heart disease, a history of heart attack or stroke, chronic kidney disease, defective immune systems and patients under immunosuppressive drugs treatment will be excluded.

Intervention groups

Group G uses garlic extract with swab once every 12 hours to treat lesions and will be visited once every two weeks by a gynecologist for improvement and possible complications and the results will be recorded in a checklist. Group C will undergo cryotherapy using liquid nitrogen under sterile conditions. Treatment is performed once a week under the supervision of a specialist and once every two weeks, patients are evaluated for improvement and the occurrence of possible complications.

Main outcome variables

Rate of Lesions recovery, recovery time and side effects are the three main outcome of the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N20**

Registration date: **2022-02-28, 1400/12/09**

Registration timing: **prospective**

Last update: **2022-02-28, 1400/12/09**

Update count: **0**

Registration date

2022-02-28, 1400/12/09

Registrant information

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0097

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-11, 1400/12/20

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A clinical study of efficacy of garlic extract versus cryotherapy in the treatment of genital wart

Public title
Treatment of genital warts with cryotherapy and garlic extract

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Genital warts (vulva, vagina and pubis) No history of treatment in the last 6 months
Exclusion criteria:
Having underlying diseases (atopy, diabetes, hypertension, ischemic heart disease, history of heart attack or stroke, chronic kidney disease) Taking immunosuppressive drugs Congenital or acquired immunodeficiency

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
100 samples will be randomly coded with computer software in two groups G and C and the codes will be recorded on raw checklists. By referring the patient with inclusion criteria, One of the checklists will be randomly selected. If the selected code is G, the patient will be in the garlic extract treatment group and if it is C, in the cryotherapy group.

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 Hamadan University of Medical Science

Street address
shahid fahmideh avenue

City
Hamadan

Province
Hamadan

Postal code
6517838697

Approval date
2021-12-11, 1400/09/20

Ethics committee reference number
IR.UMSHA.REC.1400.716

Health conditions studied

1

Description of health condition studied

Genital Wart

ICD-10 code

A63.0

ICD-10 code description

Anogenital (venereal) warts

Primary outcomes

1

Description

Lesion recovery rate

Timepoint

Before treatment and every 15 days after treatment for 8 weeks

Method of measurement

Clinical examination and observation, Scoring based on Ordinal scale: poor moderate good

Secondary outcomes

1

Description

Duration of treatment

Timepoint

Once every 15 days for 8 weeks

Method of measurement

Clinical examination

2

Description

Side effects of treatment

Timepoint

Once every 15 days for 8 weeks

Method of measurement

Clinical examination and questioning of the patient

Intervention groups

1

Description

Intervention group: Will be treated with garlic extract. In order to provide garlic extract, first, pour 20 cloves of garlic in a mixer until completely chopped, then add methanol and chloroform in a ratio of 1: 2. Add the same weight of distilled water and crush it again with a mixer. After keeping the solution at room temperature for 24 hours and in a closed container, Eventually will be filtered with paper filtering and use the extract to treat patients. . Patients will be instructed to use garlic extract once every 12 hours to treat lesions using a cotton swab.

Category

Treatment - Drugs

2

Description

Intervention group: Under cryotherapy. Cryotherapy will be performed using liquid nitrogen and under sterile conditions once a week to treat genital lesions under the supervision of a gynecologist.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Dr Mehrangiz Zamani

Street address

Pasdaran Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Shokohi

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vc_research@umsha.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Samar Moghadami

Position

Medical Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

Coach

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available