

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The comparative study of the effect of Garlic extraction with Podophyllin in the Treatment of Female Genital Warts

Protocol summary

Study aim

1. Comparison of the effect of Garlic extract on podophylline solution in treatment of female genital warts
2. Comparison of female genital warts before and at weekly intervals up to one month after the start of treatment in the intervention group with garlic extract
3. Comparison of the size of female genital warts before and at weekly intervals up to one month after the start of treatment in the intervention group with podophyllin solution
4. Comparison of female genital warts before and at weekly intervals up to one month after starting treatment in two groups of garlic extract and podophyllin solution

Design

Randomized blind, community-based, and pragmatic randomized clinical trials with parallel groups, 74 women, randomized, four-block randomized block

Settings and conduct

A daily referral to a women's office in the city of Karaj, 74 women selected by randomized block method (AABB), will be divided into two groups. During the research, the samples do not know how to divide the groups into intervention groups and the type of intervention of each group. Before the start of treatment, the size of the warts of patients will be measured using a ruler and recorded as a map. Receive treatment for 4 sessions at intervals each week for one month. The response rate will be determined based on the size of the warts.

Participants/Inclusion and exclusion criteria

Criteria for entering the study aged 18-60 years, skin disorders such as dermatitis or skin allergies, lack of systemic patients, such as diabetes, hypertension, heart disease, etc., failure to receive treatment within the past 8 weeks, lack of pregnancy or lactation, Lack of susceptibility to garlic

Intervention groups

First intervention group: Garlic extraction weekly until 4 weeks
Second intervention group: podophyllin solution weekly until 4 weeks

Main outcome variables

Genital warts size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160821029446N2**

Registration date: **2018-05-02, 1397/02/12**

Registration timing: **prospective**

Last update: **2018-05-02, 1397/02/12**

Update count: **0**

Registration date

2018-05-02, 1397/02/12

Registrant information

Name

Maryam Damghanian

Name of organization / entity

Nursing and Midwifery Faculty, Tehran University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative study of the effect of Garlic extraction with Podophyllin in the Treatment of Female Genital Warts

Public title

Comparison of the effect of Garlic extraction with Podophyllin in the Treatment of Female Genital Warts

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged 18-60 years Lack of skin disorders such as dermatitis or skin sensitization Lack of systemic patients, such as diabetes, hypertension, heart disease, etc Lack of pregnancy or lactation No treatment within the past 8 weeks Lack of sensitivity to Garlic

Exclusion criteria:**Age**

From **18 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Sample allocation in two groups of Garlic extraction and Podophyllin will be performed by using the four-point blocking method (AABB). Six possible states will be considered for the AABB letters. These 6 modes are written on 6 separate cards and the cards will be placed in a black bag. For 19 times, a card will be picked up until 76 letters written in order.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be conducted as a single blind randomized clinical trial. So the participants will not be aware of the type of treatment they receive. the medicine will be used by the researcher for the patient. In addition, the appearance of garlic extraction will be similar to podophylline and will not have the smell of garlic.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of Tehran University of Medical Sciences and Health Services

Street address

Nursing and Midwifery Faculty of Tehran University of Medical Sciences, Tohid Square, Tehran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2018-04-16, 1397/01/27

Ethics committee reference number

IR.TUMS.FNM.REC.1397.4961

Health conditions studied**1****Description of health condition studied**

Genital Warts

ICD-10 code

A63.0

ICD-10 code description

Anogenital (venereal) warts

Primary outcomes**1****Description**

Genital wart size

Timepoint

Weekly until one month

Method of measurement

ruler

Secondary outcomes

empty

Intervention groups**1****Description**

First intervention group: garlic extraction that will be used by researcher on warts after covering warts perimeter with Localized softener such as Vaseline, weekly. In each session the warts' size will be measured and recorded

Category

Treatment - Drugs

2

Description

Control group: podophylline solution that will be used by researcher on warts after covering warts perimeter with Localized softener such as Vaseline, weekly. In each session the warts' size will be measured and recorded

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Women's office

Full name of responsible person

Dr. Seyedeh Fariba Behnam

Street address

Iran, Alborz, Karaj, Shahid Beheshti, Taleghani
Crossroad, Niloufar Building

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Esmat Karimi

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Sarfallah

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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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

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available