

# 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

+98 21 6692 7171

##### Email address

m-damghanian@sina.tums.ac.ir

##### 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

##### City

Karaj

##### Province

Alborz

##### Postal code

1419733171

##### Phone

+98 26 3223 2099

##### Email

zahrayesarfallah@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Esmat Karimi

##### Street address

Number 23, Dameshgh Street, Valiasr Street, Tehran,  
Iran

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##### Province

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##### Phone

+98 21 6105 4222

##### Email

maryam\_damghanian@yahoo.com

##### 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

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

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##### Position

Associate Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Midwifery

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

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**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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Towhid Square, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**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