

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison the effect of herbal product " Myrtus communis " with placebo on the treatment of genital warts in women

Protocol summary

Summary

The main aim of this study is to determine the effect of herbal product "Myrtus Communis" in the treatment of genital warts in women. The study is a Double blind randomized clinical trial, two centers with placebo control. Female patient aged 18 to 50 years with vaginal or cervical wart are enrolled, patient with candida, trichomona and other infections vaginitis or cervicitis and recognized immunodeficiency or autoimmune disease, HIV-positive patients, Long-term use of corticosteroids or immunosuppressive, smoking, pregnancy, those who had CIN2 and CIN3 in cervix biopsy are excluded. The total number of 60 patients is taken into account that randomly will be divided into two groups: intervention and control. The intervention group are treated with 60 Myrtus vaginal suppositories one every night except during menstruation period. The control group are treated with 60 placebo vaginal suppositories one every night except during menstruation period. The dietary recommendations based on iranian traditional medicine will be given to all patient. The study period is three months. The main outcome measure of the study is HPV test and related consequences outcome are lesion size, clinical symptom, drug side effects. Candidates are checked for HPV virus, lesion size at the baseline and the end of the study, for clinical symptom at the baseline, end of the first and the second and the third month of the study, for drug side effects during the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092429936N1**

Registration date: **2016-12-23, 1395/10/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-12-23, 1395/10/03

Registrant information

Name

Zahra Nikakhtar

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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nikakhtarz1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology Mashhad University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of herbal product " Myrtus communis " with placebo on the treatment of genital warts in women

Public title

The effects of traditional medicine product in genital wart

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Female patient with vaginal or cervical wart; age between 18 to 50 years
Exclusion criteria: patient with Candida, trichomona and other infections vaginitis or cervicitis; patients with recognized immunodeficiency or autoimmune disease; HIV positive patients; Long-term use of corticosteroids or immunosuppressive; smoking; pregnancy; those who had CIN2 and CIN3 in cervix biopsy; Lack of satisfaction in every stage of the study

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research and Technology
Mashhad University of Medical Sciences, Building
Qureshi, Daneshgah Ave.

City

Mashhad

Postal code

Approval date

2016-08-27, 1395/06/06

Ethics committee reference number

IR.MUMS.REC.1395.299

Health conditions studied

1

Description of health condition studied

Genital wart

ICD-10 code

A63.0

ICD-10 code description

Anogenital (venereal) warts

2

Description of health condition studied

Cervix dysplasia

ICD-10 code

N87.0

ICD-10 code description

Mild cervical dysplasia

3

Description of health condition studied

vaginal dysplasia

ICD-10 code

N89.0

ICD-10 code description

Mild vaginal dysplasia

4

Description of health condition studied

papilloma of cervix

ICD-10 code

D26.0

ICD-10 code description

Other benign neoplasms of uterus

Primary outcomes

1

Description

HPV virus

Timepoint

Baseline, the end of the study

Method of measurement

HPV-PCR test

2

Description

Lesion size

Timepoint

Baseline, the end of the study

Method of measurement

Colposcopy

Secondary outcomes

1

Description

Clinical symptom

Timepoint

Baseline, end of the first and the second and the third month of the study

Method of measurement

According to the patient's symptoms

2

Description

Drug Side Effects

Timepoint

During the study

Method of measurement

According to the patient's symptoms

Intervention groups

1

Description

Patients are treated with 60 Myrtus vaginal suppositories one every night except during menstruation period in the intervention group . Disease status will be reviewed at the beginning and the end of the study.

Category

Treatment - Drugs

2

Description

Patients are treated with 60 placebo vaginal suppositories one every night except during menstruation period in the control group. Disease status will be reviewed at the beginning and the end of the study.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qaem Educational, Research and Treatment Center

Full name of responsible person

Zahra Nikakhtar

Street address

Faculty of Iranian Traditional Medicine and Complementary, Opposite the Mehran sports hall, East Razi Ave.

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology
Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

Vice Chancellor for Research and Technology Mashhad
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

Name of organization / entity

Faculty of Iranian Traditional Medicine and
Complementary of Mashhad University of Medical
Sciences

Full name of responsible person

Zahra Nikakhtar

Position

PhD student of Iranian Traditional Medicine and
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Other areas of specialty/work

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Web page address**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