

# 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

+98 51 3853 6780

###### Email address

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.

#### **City**

mashhad

### 2

### **Recruitment center**

#### **Name of recruitment center**

Faculty of Iranian Traditional Medicine and Complementary

#### **Full name of responsible person**

Zahra Nikakhtar

#### **Street address**

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

### **City**

mashhad

## **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

#### **Street address**

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

#### **City**

Mashhad

#### **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  
Complementary

#### **Other areas of specialty/work**

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**Full name of responsible person**

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**Position**

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**Postal code****Phone**

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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*