

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The comparison between gel containing *Prunella vulgaris* extract and Acyclovir on treatment of labial herpes in patients with recurrent herpes labialis

#### Protocol summary

##### Summary

This study is a double-blind, randomized, single center, controlled trial on people aged 18 to 70 years old that are coming to Naghavi Hospital suffering from recurrent herpes labialis for less than 12 hours. Participants must not have used the antiviral drug in the past two weeks and must not have a history of immunotherapy over the last year or immune system stimulation in the last month. Other mucocutaneous disorders and a history of RAS are among exclusion criteria. There will be 80 participants randomly divided into two groups of herbal gel containing *Prunella vulgaris* extract or Acyclovir. A thin layer of both will be applied every 3 hours (6 times per day) to the lesion. The participants will be visited at baseline and six days after the start of the study and will be followed in the second and fourth day after the beginning of the study by telephone. Clinical information and severity of burning and itching, soreness, tingling, and other possible side effects of medications will be recorded and compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016021412438N16**

Registration date: **2016-03-03, 1394/12/13**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-03-03, 1394/12/13

##### Registrant information

###### Name

Mohsen Taghizadeh

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

taghizadeh\_m@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Barij Research Center of Medicinal plants

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2016-08-22, 1395/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison between gel containing *Prunella vulgaris* extract and Acyclovir on treatment of labial herpes in patients with recurrent herpes labialis

##### Public title

The effect of gel containing *Prunella vulgaris* extract on labial herpes

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion: People 18 to 70 years old with recurrent herpes labialis that Less than 12 hours have passed vesicate. Exclusion criteria: Pregnancy and lactatin; use the antiviral drug in the past two weeks; have a history

of immunotherapy in the last year; stimulating the immune system in the last month; Other mucocutaneous disorders; history of RAS ;history of allergy to the plant used in the study of allergic reaction during the study

#### **Age**

From **18 years** old to **70 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **80**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double 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 Kashan University of Medical Sciences

###### **Street address**

Medical college, Ghotb Ravandi boulevard, Kashan

###### **City**

Kashan

###### **Postal code**

##### **Approval date**

2016-02-03, 1394/11/14

##### **Ethics committee reference number**

IR.KAUMS.REC.1394.148

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

recurrent herpes labialis

##### **ICD-10 code**

B00.1

##### **ICD-10 code description**

Herpesviral vesicular dermatitis

### **Primary outcomes**

#### **1**

##### **Description**

Clinical symptoms of blisters

##### **Timepoint**

Baseline and End-of-trial

##### **Method of measurement**

Observation

#### **2**

##### **Description**

Burning

##### **Timepoint**

At days 0, 2, 4, 7

##### **Method of measurement**

VAS

#### **3**

##### **Description**

itching

##### **Timepoint**

At days 0, 2, 4, 7

##### **Method of measurement**

VAS

#### **4**

##### **Description**

Soreness

##### **Timepoint**

At days 0, 2, 4, 7

##### **Method of measurement**

VAS

#### **5**

##### **Description**

Tingling

##### **Timepoint**

At days 0,2,4,7

##### **Method of measurement**

VAS

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

intervention: topical herbal gel, 6 times a day (every 3 hours) for a week

##### **Category**

Treatment - Drugs

## 2

### Description

control: topical acyclovir, 6 times a day (every 3 hours)  
for a week

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Naghavi Hospital

##### Full name of responsible person

Dr Mohammad Hajijafari

##### Street address

##### City

Kashan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Barij Research Center of Medicinal Herbs

##### Full name of responsible person

Miss L.Hejazi

##### Street address

Km. 44 of Kashan - Delijan Rd, Mashhad-e- Ardehal

Kashan

##### City

Kashan

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Barij Research Center of Medicinal Herbs

##### Proportion provided by this source

##### 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*

### 2

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Kashan University of

Medical Science

##### Full name of responsible person

Dr Gholam Ali Hamidi

##### Street address

Medical college, Ghotb Ravandi boulevard, Kashan

##### City

Kashan

##### 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 of Kashan University of

Medical Science

##### Proportion provided by this source

##### 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

Kashan University of Medical Sciences

##### Full name of responsible person

Dr.M.Taghizadeh

##### Position

PHD

##### Other areas of specialty/work

##### Street address

Medical college, Ghotb Ravandi boulevard, Kashan

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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Barij Research Center of Medicinal Herbs  
**Full name of responsible person**  
M.Mahlouji  
**Position**  
Clinical Expert  
**Other areas of specialty/work**  
**Street address**  
Km. 44 of Kashan - Delijan Rd, Mashhad-e- Ardehal  
Kashan  
**City**  
Kashan  
**Postal code**  
**Phone**

## 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*