

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

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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

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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 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

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Person responsible for updating data

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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