

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparative evaluation of therapeutic effects (improving indicators) related to Recurrent Herpes Labialis using Nano and moco adhesive formulation of acyclovir and acyclovir\_clobetasole

#### Protocol summary

##### Study aim

Comparative evaluation of therapeutic effects related to Recurrent Herpes Labialis using Nano and moco adhesive formulation of acyclovir and acyclovir\_clobetasole

##### Design

The study is a double-blind clinical trial. 80 patients with recurrent labial herpes were selected from among those who referred to the diagnosis department of Isfahan Dental School, and the zero phase was performed on them.

##### Settings and conduct

This study was conducted in Isfahan Dental Faculty in 2016-2017. The current study is a double-blind clinical trial, and the researcher and the patient are not aware of the type of drug used, and the drugs were given to them in the form of a.b.c.d.

##### Participants/Inclusion and exclusion criteria

1) The age range of the patient is between 18 and 60 years. 2) Maximum 48 hours have passed since the appearance of the lesion. 3) The lesion is recurrent. 4) The patient does not take any antiviral, anti-inflammatory, steroid or painkillers 5) The patient should not use any topical products such as lip moisturizing cosmetics and sun cream in the lesion area during the treatment and should not perform any manipulations such as scratching or facial correction in the area. 6) Damage in the stage of Be a vesicle. 7) The size of the lesion should be  $\leq 1$  cm. Exclusion criteria: 1) having drug allergy 2) using topical or systemic medication to treat recurrent herpes labialis in the last 4 weeks. 3) suffering from systemic diseases or liver and kidney failure diseases. 4) using Birth control pills and breastfeeding 5) Suffering from immunodeficiency and acquired diseases

##### Intervention groups

Patients with recurrent labial herpes referred to the diagnostic department of Isfahan Dental School

##### Main outcome variables

The amount of pain and the time to close the scab and the time to heal the lesions

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230926059521N1**

Registration date: **2023-11-14, 1402/08/23**

Registration timing: **retrospective**

Last update: **2023-11-14, 1402/08/23**

Update count: **0**

##### Registration date

2023-11-14, 1402/08/23

##### Registrant information

##### Name

solmaz mohamadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3322 5243

##### Email address

solmazmohamadi.dnt2@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-08-23, 1396/06/01

##### Expected recruitment end date

2018-08-23, 1397/06/01

##### Actual recruitment start date

2017-08-23, 1396/06/01

**Actual recruitment end date**

2018-08-23, 1397/06/01

**Trial completion date**

2019-02-20, 1397/12/01

**Scientific title**

Comparative evaluation of therapeutic effects (improving indicators) related to Recurrent Herpes Labialis using Nano and moco adhesive formulation of acyclovir and acyclovir\_clobetasole

**Public title**

Comparative evaluation of therapeutic effects (improving indicators) related to Recurrent Herpes Labialis using Nano and moco adhesive formulation of acyclovir and acyclovir\_clobetasole

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

(The lesion is recurrent (secondary) and not primary in any case. 2) The age range of the patient should be between 18 and 60 years. does not. 5) The patient should not use any lip moisturizing topical cosmetics or sun cream in the lesion area during the treatment, and should not perform any manipulations such as scratching or facial modification in the area. 6) The lesion should be in the papule-vesicle stage

**Exclusion criteria:**

Having an allergy to acyclovir or a history of severe allergy to other drugs. 2) Using topical or systemic drugs to treat recurrent herpes labialis in the last 4 weeks. 3) Suffering from systemic diseases or liver and kidney failure diseases. 4) Using Contraceptive pills and breastfeeding. 5) suffering from immunodeficiency and acquired diseases

**Age**From **18 years** old to **60 years** old**Gender**

Both

**Phase**

0

**Groups that have been masked**

- Participant
- Investigator

**Sample size**Target sample size: **80**Actual sample size reached: **80**

More than 1 sample in each individual

Actual sample size in each individual: **1**

80 patients with recurrent labial herpes were selected from among those who referred to the diagnostic department of Isfahan Faculty of Dentistry. Inclusion criteria: 1) The age range of the patient is between 18 and 60 years old. 2) Maximum 48 hours have passed since the appearance of the lesion. 3) The lesion is recurrent (secondary). 4) The patient does not have any antiviral drugs, anti 5) The patient should not use any topical substances such as lip moisturizing cosmetics and sun cream in the lesion area during the treatment, and should not perform any manipulations such as scratching

or facial correction in the area. 6. ) the lesion is in the vesicle stage Exclusion criteria: 1) having drug allergy 2) using topical or systemic medication to treat recurrent herpes labialis in the last 4 weeks. 3) suffering from systemic diseases or liver and kidney failure diseases. 4) using Contraceptive pills and breastfeeding 5) suffering from immunodeficiency and acquired diseases, before any action, the work steps were explained to the patients and the written informed consent (Appendix 1, 2) was filled by them.

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The researcher and the patient were not aware of the type of medicine received from the beginning of the treatment until the end, and the pharmacist provided the medicine in the form of an ointment with labels that had the code a, b, c, or d, and only the pharmacist and the statistical analyzer of the type of medicine related to each Labels were known, the researcher gave the drugs to the study participants and the results related to each type of label were given to the statistical analyzer

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of isfahan University of Medical Sciences

**Street address**

isfahan University of Medical Sciences

**City**

isfahan

**Province**

Isfahan

**Postal code**

81745319

**Approval date**

2017-08-23, 1396/06/01

**Ethics committee reference number**

ir.mui.rec.1397.3.081

**Health conditions studied****1****Description of health condition studied**

Recurrent herpes labialis

ICD-10 code  
ICD-10 code description

## Primary outcomes

1

### Description

The amount of pain or burning was calculated and recorded by the patient with a score scale, and the time of dressing the scab and recovery time was recorded by the clinician.

### Timepoint

1st to 7th day after delivery of medicine

### Method of measurement

The amount of pain or burning was calculated and recorded by the patient with a score scale, and the time of dressing the scab and recovery time was recorded by the clinician.

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: 80 patients with recurrent labial herpes

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

isfahan univercity of medical science

#### Full name of responsible person

solmaz mohamadi

#### Street address

isfahan univercity of medical science

#### City

isfahan

#### Province

Isfahan

#### Postal code

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#### Web page address

http://research.mui.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

mansur siavash

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### Grant name

### Grant code / Reference number

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

No

### Title of funding source

Isfahan University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Private

### 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

Esfahan University of Medical Sciences

#### Full name of responsible person

solmazmohamadi

#### Position

dentist

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Dentistry

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

zahra golestannezhad

**Position**

associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Latest degree**

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## 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**

Publication of individual data according to the researcher's opinion is not allowed

**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**

Undecided - It is not yet known if there will be 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