

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of remission index of nanofiber loading acyclovir- melisa and nanofiber loading acyclovir and mucoadhesive cream formula on Recurrent-Herpes-Labialis

#### Protocol summary

##### Study aim

Comparison of therapeutic effects of acyclovir- melissa nanofiber patch and cream with acyclovir nanofiber patch and cream on recurrent herpes labialis

##### Design

Four arm parallel groups randomized clinical trial, double-blinded, phase 2 on 80 patients, randomization was employed by permuted block randomization method with a block size of 4

##### Settings and conduct

This study was performed in the Department of Oral Diseases, Isfahan University of Medical Sciences. The lesions were diagnosed by a specialist and informed consent was obtained from the patients. The 4 study groups used 15 nanofiber patches of acyclovir-melissa, acyclovir-melissa cream, 15 nanofiber patches of acyclovir and an acyclovir cream respectively, three times a day for 5 days. Patients recorded symptoms on a daily basis and were asked to prepare images from the lesion daily. As soon as evidence of healing and crusting was observed in the images, the patient was referred for clinical examinations. Patients and clinician were unaware of the contents of the packages.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: secondary lesions and in the vesicular stage (size <1 cm) Exclusion criteria: allergy to acyclovir and other drugs, systemic and inherited or acquired immunodeficiency disease, pregnancy, lactation, use of contraceptives, antiviral and anti-inflammatory drugs, steroids and analgesics

##### Intervention groups

Four intervention groups of acyclovir-melissa nanofiber patch, acyclovir- nanofiber patch, acyclovir-melissa acyclovir-melissa and acyclovir cream

##### Main outcome variables

The formulations of acyclovir- Melissa nano-patch and acyclovir- Melissa cream and acyclovir nano-patch

caused a reduction in the pain of lesions, compared to acyclovir routine formulation. The crusting time in acyclovir- Melissa nano-patch and cream group was less than both acyclovir groups.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141124020073N3**

Registration date: **2022-02-20, 1400/12/01**

Registration timing: **retrospective**

Last update: **2022-02-20, 1400/12/01**

Update count: **0**

##### Registration date

2022-02-20, 1400/12/01

##### Registrant information

##### Name

Zahra Golestan nejad

##### Name of organization / entity

Oral medicine department associate professor

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 2814

##### Email address

golestannejad@dnt.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-11, 1400/06/20

##### Expected recruitment end date

2021-12-11, 1400/09/20

**Actual recruitment start date**

2021-09-20, 1400/06/29

**Actual recruitment end date**

2021-11-26, 1400/09/05

**Trial completion date**

empty

**Scientific title**

Comparison of remission index of nanofiber loading acyclovir- melisa and nanofiber loading acyclovir and mucoadhesive cream formula on Recurrent-Herpes-Labialis

**Public title**

Effect of acyclovir-melissa nanofiber patch in treatment of recurrent herpes labialis

**Purpose**

Treatment

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

Maximum interval of 48 hours since the emergence of the lesion Having a recurrent lesion (i.e., secondary) Receiving no antiviral, anti-inflammatory, steroid, or analgesic drugs Vesicular stage of the lesion and lesion size <1 cm

**Exclusion criteria:**

Allergies to the used herbal medicines Hepatic, renal, or systemic diseases Use of birth control pills Breastfeeding

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **80**

Actual sample size reached: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The selected patients were randomly divided into four groups. The first group received a pack containing 15 acyclovir 5%-Melissa 1% nanopatches; the second group received a tube containing acyclovir 5%-Melissa 1% cream; the third group received 15 nanopatches of acyclovir 5%; and the fourth group received acyclovir 5% cream. Considering small recruited sample size and for overall balance reasoning between the four study arms, the recruited patients were randomized employing permuted block randomization method with a block size of 4.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patients and the clinicians were unaware about the content of the packages containing nanofiber patches and the creams.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Research ethics committee of Isfahan University of Medical Sciences

**Street address**

Vice counselor for research and technology, Isfahan University of Medical Sciences, Hezar jerib St.

**City**

Isfahan

**Province**

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**Postal code**

81745319

**Approval date**

2021-02-28, 1399/12/10

**Ethics committee reference number**

IR.MUI.REC.1397.3.079

**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**

Symptoms of patient discomfort (pain, itching, burning sensation)

**Timepoint**

Daily measurement of the symptoms from the beginning of treatment (baseline) until the symptoms disappeared

**Method of measurement**

Using a numerical scale, ranging from 0 to 10

**2****Description**

Crusting time

**Timepoint**

As soon as evidence of crusting was observed in the daily images taken and sent by patients, the patient was

referred for clinical examinations

#### **Method of measurement**

Clinical examination

### **3**

#### **Description**

Healing time

#### **Timepoint**

As soon as evidence of healing was observed in the images, the patient was referred for clinical examinations

#### **Method of measurement**

Clinical examination

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: acyclovir-melissa nanofiber patch: Active ingredients are acyclovir in the class of antiviral drugs, and Melissa Officinalis a herb containing polyphenolic compounds with anti-inflammatory and anti-viral properties. main chemical composition consists of polyvinyl alcohol polymer, acyclovir5% and melissa1%, made in "Rahesh Daruye Novin" company, used once in a day for 5 days at the site of the lesion

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Intervention group: acyclovir-melissa cream: Active ingredients are acyclovir5% in the class of antiviral drugs, and Melissa Officinalis1% a herb containing polyphenolic compounds with anti-inflammatory and anti-viral properties, made in "Iran Daru" pharmaceutical company, used three times in a day for five days at the site of the lesion

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

Intervention group: acyclovir nanofiber patch: Active ingredient is acyclovir in the class of antiviral drugs, main chemical composition consists of polyvinyl alcohol polymer and acyclovir, made in "Rahesh Daruye Novin" company, used once in a day for 5 days at the site of the lesion

#### **Category**

Treatment - Drugs

### **4**

#### **Description**

Intervention group: acyclovir cream 5%, Active ingredient is acyclovir in the class of antiviral drugs, made in "Iran Daru" pharmaceutical company, used three times in a day for five days at the site of the lesion

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

School of Dentistry, Isfahan University of Medical Sciences

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

Zahra Golestannejad

##### **Street address**

School of Dentistry, Isfahan University of Medical Sciences, Hezar Jerib St.

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##### **Phone**

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##### **Email**

golestannejad@dnt.mui.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

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

Nakisa Torabinia

##### **Street address**

Faculty of Dentistry, Isfahan University of Medical Sciences, Hezar Jerib St.

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research@dnt.mui.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

397079

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

Yes

##### **Title of funding source**

Esfahan University of Medical Sciences

##### **Proportion provided by this source**

**Public or private sector**

Public

**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**

zahra Golestannejad

**Position**

Associate Professor

**Latest degree**

Specialist

**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 Golestannejad

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Email****Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dorna Sarfaraz

**Position**

Dentist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Individual data of study participants can be shared after unidentifying individuals

**When the data will become available and for how long**

The access period starts from the time the results are printed

**To whom data/document is available**

The data will be available to researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

The use of participants' personal data and study documents is allowed only for scientific purposes and study simulation

**From where data/document is obtainable**

To access the data, refer to the person in charge of updating the information.

**What processes are involved for a request to access**

**data/document**

If necessary, the applicant sends an email to the person in charge of updating the information, requesting access

to the data file, and the data will be sent to the applicant's email within 1 to 2 days.

**Comments**