Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 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 respectiveyl,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)

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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.
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Isfahan
Province
Isfehan
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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

100

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
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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