Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Nov 2026

Comparative evaluation of teraputic effects (improving indicators) related to Recurrent HerpesLabialis using Nano and mocoadhesive formulation of acyclovir and acyclovir_clobetasole

Protocol summary

Study aim

Comparative evaluation of teraputic effects related to Recurrent Herpes Labialis using Nano and mocoadhesive 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 ≤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)

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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 teraputic effects (improving indicators) related to Recurrent HerpesLabialis using Nano and mocoadhesive formulation of acyclovir and acyclovir_clobetasole

Public title
Comparative evaluation of teraputic effects (improving indicators) related to Recurrent HerpesLabialis using Nano and mocoadhesive 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
Isfehan
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
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Sponsors / Funding sources

1

Sponsor
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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
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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