

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Physicochemical characterization and clinical evaluation of final formulation of Shallomin liposomal gel on cold sore

Protocol summary

Study aim

Physico-chemical Characterization and clinical evaluation of Shallomin Liposomal Gel final formulation on cold sore

Design

Clinical trial with a control group, parallel groups design of 45 patients, double-blind randomized, zero phase, randomized using a table of random numbers

Settings and conduct

In this study researcher, participants and physician were blind. The subjects in both treatment groups were asked to use the administered medicine on the cold sore every hour until the tingling sensation and sores healed. placebo (only liposomal gel) was prepared in similar looking containers and was administered for the control group and asked them to apply it hourly on sores. Dermatologist examined the sores in both treatment groups during 12, 24, 48 and 72 hours after initiation of intervention until cold sores healed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the incidence of cold sore during the last 24 hours without treatment Exclusion criteria: self-medication after cold sore incidence

Intervention groups

The first group: Administration of placebo The second group: Treatment with acyclovir ointment The third group: Treatment with shallomin liposomal gel Participants were male and female students of Ahvaz Jundishapur university of medical sciences who were examined by dermatologist and cold sore had been diagnosed for them. All volunteers were shown cold sores within 24 hours before checkup. Participants were randomly divided to three groups each included 15 students. Two groups were randomly chosen as treatment groups (first group were exposed to treatment with acyclovir and second group treated with shallomin liposomal gel) and third group was selected as control group (with administration of placebo).

Main outcome variables

Shallomin concentration, percentage of release, the

mean of liposome size, lipid ratio, the amount of shallomin encapsulated liposome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200819048457N1**

Registration date: **2020-10-06, 1399/07/15**

Registration timing: **retrospective**

Last update: **2020-10-06, 1399/07/15**

Update count: **0**

Registration date

2020-10-06, 1399/07/15

Registrant information

Name

Zahra Farshadzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3333 0250

Email address

zahra.farshadzadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

2015-09-23, 1394/07/01

Actual recruitment end date

2018-05-15, 1397/02/25

Trial completion date

2018-05-15, 1397/02/25

Scientific title

Physicochemical characterization and clinical evaluation of final formulation of Shallomin liposomal gel on cold sore

Public title

Evaluation of Moosir liposomal extract on cold sore

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: the incidence of cold sore during the last 24 hours without treatment

Exclusion criteria:

Exclusion criteria: self-medication after cold sore incidence

Age

From **20 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Not randomized

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

Double blinded

Blinding description

In present study, clinical caregivers, researchers, outcome evaluators and participants are blind

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Ahvaz jundishapur University of Medical Sciences

Street address

Ahvaz jundishapur university of medical sciences,

Esfand Ave, Farvardin BLv, Golestan Highway

City

Ahvaz

Province

Khouzestan

Postal code

15794 - 61357

Approval date

2015-09-19, 1394/06/28

Ethics committee reference number

IR.ajums.rec.1394.410

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

Cold sore

ICD-10 code

B00

ICD-10 code description

Herpesviral [herpes simplex] infections

Primary outcomes**1****Description**

wound healing

Timepoint

6, 12, 24 and 72 hours after treatment with shallomin liposomal gel

Method of measurement

Ocular

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Treatment using acyclovir ointment (5%), every 6h for 72h. Intervention group 2: Treatment using shallomin liposomal gel (1%), every 6 h for 72h.

Category

Treatment - Drugs

2**Description**

Control group: Treatment using placebo every 6 h for 72h.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Reza Yaghoobi

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Golestan hospital, Farvardin Blvd, Golestan region

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mansour Amin

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Microbiology

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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

There is no more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results will be presented in the form of a research paper

When the data will become available and for how long

from January 2021

To whom data/document is available

Researchers Physicians Pharmacists

Under which criteria data/document could be used

In order to produce the drug and in coordination with the responsible researcher, the documents can be used

From where data/document is obtainable

Dr Mansour Amin- Jundishapur University of Medical Sciences

What processes are involved for a request to access data/document

There is no specific process for obtaining documents, all documents can be obtained by referring to the researcher in charge

Comments