Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of topical nanoliposomes gel containing curcumin (Sinanumin) in improving stomatitis aphthous in patients with Behcet's disease compared to Triamcinolone Acetonide

Protocol summary

Study aim
Evaluation and comparison the gel effect of topical nanoliposomes containing curcumin (cyanomine) and triamcinolone acetone on oral aphthous patients

Design
Clinical trial with control group, parallel groups, double blind, randomized and phase 3 clinical trials

Settings and conduct
This study was performed on patients with Behcet's syndrome with oral aphthous who referred to Imam Reza and Ghaem hospital in Mashhad from 2018 to 2020 based on inclusion and exclusion criteria. Patients were randomly divided into two groups of 50 (group 1) (using Sinanumin nanodevelopment gel) and group 2 (using triamcinolone acetone gel). They take. On day 0, 3, 7 patients were examined for the number and size of wounds and daily pain score. Then the two groups were compared based on the results of wound size, number of ulcers, duration of wound and pain score and were statistically analyzed. were See also be

Participants/Inclusion and exclusion criteria
Inclusion criteria: persons with sufficient knowledge and literacy to understand the explanations provided for treatment; patients aged between 14 and 50 years old. Exclusion criteria: traumatic ulcer; patients with dentures; pests in inaccessible areas; patients who suffer from any systemic disease causing immunodeficiency (diabetes and ESRD ...); patients with any major disease in the past; use of any systemic treatment, including use of any type of immunosuppressive drug; patients who are allergic to curcumin at baseline or during the study; pregnant or lactating women; people who cannot continue their studies for personal or social reasons.

Intervention groups
In the intervention group, topical nanoliposomes containing curcumin (cyanomine) plus colchicine and in the control group triamcinolone acetone plus colchicine were used to improve oral aphthous patients.

Main outcome variables
Number of ulcer; size of ulcer; pain score; duration of ulcer

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190308042966N1**
Registration date: **2019-10-30, 1398/08/08**
Registration timing: **prospective**

Last update: **2019-10-30, 1398/08/08**
Update count: **0**

Registration date
2019-10-30, 1398/08/08

Registrant information

Name
Seyed farzam Mircheraghi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3870 0349

Email address
mrchrgh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-22, 1398/10/01

Expected recruitment end date
2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of topical nanoliposomes gel containing curcumin (Sinanumin) in improving stomatitis aphthous in patients with Behcet's disease compared to Triamcinolone Acetonide

Public title

Effect of topical nanoliposomes gel containing curcumin (Sinanumin) in improving stomatitis aphthous in patients with Behcet's disease compared to Triamcinolone Acetonide

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between the age of 14 and 50 years with sufficient literacy and knowledge to provide explanations

Exclusion criteria:

Traumatic oral ulcer Patients with dentures Aphthous in inaccessible areas Patients who suffer from any systemic disease causing immunodeficiency (diabetes and ESRD ...) Patients with any major disease in the past Use of any systemic treatment, including use of any type of immunosuppressive drug Patients who are allergic to sinanomine at baseline or during the study Pregnant or lactating women People who cannot continue their studies for personal or social reasons

Age

From **14 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The method used to generate random allocation sequences using a random number table using randomiz.com so that envelopes are prepared and printed by a member of the Random Numbers Research Team with the help of Randomaize.com. Will take. The envelope door will be closed and its contents not visible from the outside. Then, the purpose of the study is first explained to the person who meets the requirements, and if the person wishes to sign the informed consent form, remove the envelope and then open it and enter the intervention or control group based on the contents of the individual envelope

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is unaware of the treatment and the blinding of the analyzer and the patient (double blind) is performed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of School of Medicine-Mashhad University of Medical Sciences

Street address

University Street, Central Building of Mashhad University of Medical Sciences (Qurishi)

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2019-05-28, 1398/03/07

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.380

Health conditions studied

1

Description of health condition studied

Behcet's disease - Recurrent Oral aphthous

ICD-10 code

K12.0 M35

ICD-10 code description

Behcet's disease

Primary outcomes

1

Description

Mean pain score between two groups after intervention

Timepoint

Day 0, 3 and 7

Method of measurement

Caliper Vernier Ruler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, Sina nanomedicine gel is used.Topical nano-liposomes containing curcumin (cyanomine) were made at the Nanotechnology Research Center of Mashhad University of Medical Sciences by Dr. Mahmoud Reza Jafari. The drug is made of curcumin yellow active ingredient. intervention grou benefit from standard treatment of Behcet's oral aphthous treatment, including colchicine. On day 0, 3, 7 patients were examined for the number and size of wounds and daily pain score. On day 0 the patient was examined for the number and size of the wounds and the pain score. The longest wound diameter measured using a sterile Vernier caliper is recorded as the wound size, and pain scores are reported using the Visual Analogue Scale (VAS) of zero to 10. Patients are also examined on days 3 and 7 to check for a decrease in the number and size of wounds. Pain scores are also recorded daily.

Category

Treatment - Drugs

2

Description

Control group: In the control group is used triamcinolone acetone gel. Control group benefit from standard treatment of Behcet's oral aphthous treatment, including colchicine. On day 0, 3, 7 patients were examined for the number and size of wounds and daily pain score. On day 0 the patient was examined for the number and size of the wounds and the pain score. The longest wound diameter measured using a sterile Vernier caliper is recorded as the wound size, and pain scores are reported using the Visual Analogue Scale (VAS) of zero to 10. Patients are also examined on days 3 and 7 to check for a decrease in the number and size of wounds. Pain scores are also recorded daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital - Ghaem hospital

Full name of responsible person

Seyed Farzam Mircheraghi

Street address

International Students Admission Committee, International Office, Chancellory Building, Mashhad University of Medical Sciences, Mashhad, P.O. Box: 91735-951, I. R. IRAN.

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9137913316

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mircheraghif961@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

International Students Admission Committee, International Office, Chancellory Building, Mashhad University of Medical Sciences, Mashhad, P.O. Box: 91735-951, I. R. IRAN

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vcresearch@mums.ac.ir

Web page address

http://v-research.mums.ac.ir/index.php

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person
Seyed farzam Mircheraghi
Position
Rezident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Seyed Farzam Mircheraghi
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Internal resident
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available