

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 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

### 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.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913316

##### Phone

+98 51 3034 5831

##### Email

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

##### City

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##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 2081

##### Email

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

**Street address**

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International Office, Chancellory Building, Mashhad  
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mircheraghif961@mums.ac.ir

**Person responsible for scientific 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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mircheraghif961@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Seyed Farzam Mircheraghi

**Position**

Internal resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

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0098513870349

**Email**

mircheraghif961@mums.av.ir

**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