

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Preparation and clinical evaluation of a novel colchicine mucoadhesive gel for the treatment of aphthous stomatitis: An experimental study and a double blinded randomized clinical trial

#### Protocol summary

##### Study aim

Preparation and clinical evaluation of a novel colchicine mucoadhesive gel for the treatment of aphthous stomatitis

##### Design

In this study, patients with aphthous stomatitis are selected through recall in pharmacies, physicians' offices and social networks according to the inclusion criteria and will enter the study after obtaining written consent. Patients' information including age, sex, weight, underlying diseases, and medications will be recorded. Patients using the RAND function of Excel software are randomly divided into two groups, including the colchicine group and the placebo group (basal posterior mucosa gel without colchicine) in each group of 25 people. Patients will use the drug twice a day at the rate of one drop per pest. At the beginning of treatment and after every 2 days for 10 days, the condition of aphthous lesions will be checked

##### Settings and conduct

A double-blind randomized controlled clinical trial in Yazd province on 50 patients in the control and intervention groups

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with aphthous stomatitis starting up to two days, No pregnancy and lactation, patients between 18\_65 years old, No history of allergies to colchicine Exclusion criteria: Patients with skin diseases, Sensitivity to colchicine or any of components of the product, Do not use the drug for two consecutive days, Exacerbation of the aphthous stomatitis

##### Intervention groups

In the present study, patients will be divided into two groups: colchicine mucoadhesive gel receiving group, Base mucoadhesive gel receiving group.

##### Main outcome variables

Pain, inflammation, aphthous lesions size, number of

aphthous lesions

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191106045356N8**

Registration date: **2021-08-06, 1400/05/15**

Registration timing: **prospective**

Last update: **2021-08-06, 1400/05/15**

Update count: **0**

##### Registration date

2021-08-06, 1400/05/15

##### Registrant information

##### Name

Mohsen Zabihi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3820 3865

##### Email address

mzabihi100@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-21, 1400/05/30

##### Expected recruitment end date

2021-11-21, 1400/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Preparation and clinical evaluation of a novel colchicine mucoadhesive gel for the treatment of aphthous stomatitis: An experimental study and a double blinded randomized clinical trial

**Public title**

Preparation and clinical evaluation of a novel colchicine mucoadhesive gel for the treatment of aphthous stomatitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with aphthous stomatitis starting up to two days  
Patient between 18-65 years old  
No pregnancy and lactation  
No history of allergies to colchicine

**Exclusion criteria:**

Patients with skin diseases  
Sensitivity to colchicine or any of the components of the product  
Do not use the drug for two consecutive days  
Exacerbation of the aphthous stomatitis

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is performed based on the RND function of Excel software and patients are divided into two groups A and B. The drug and placebo are uniform and coded in terms of the shape of the drug and the drug container, and the patient and the physician prescribing the drug and the evaluator do not know the composition and content of each drug container.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Different groups of drugs are placed in uniform and coded containers, and the prescribing physician and the evaluator do not know the composition and content of each drug container.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Shahid Sadoughi University of Medical Sciences

**Street address**

Alem sq.

**City**

Yazd

**Province**

Yazd

**Postal code**

۸۹۱۶۹۷۸۴۷۷

**Approval date**

2021-08-21, 1400/05/30

**Ethics committee reference number**

در حال دریافت کد اخلاق هستیم. لطفاً دیگر ایتیم ها را بررسی فرمایید.  
Ethics committee of Shahid Sadoughi University of Medical Sciences

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

Aphthous stomatitis

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Severity of pain

**Timepoint**

At the beginning of treatment and after every 2 to 10 days, the condition of aphthous lesions is evaluated for pain intensity (score 0 to 4).

**Method of measurement**

Scoring pain using a questionnaire

**2****Description**

Redness and inflammation

**Timepoint**

At the beginning of treatment and after every 2 to 10 days, the condition of aphthous lesions is evaluated for the severity of redness and inflammation (score 0 to 4).

**Method of measurement**

Scoring severe redness and inflammation using a questionnaire

### 3

#### **Description**

Total area of aphthous lesions

#### **Timepoint**

At the beginning of treatment and after every 2 to 10 days, the condition of the aphthous lesions is evaluated in terms of the total area of the aphthous lesions.

#### **Method of measurement**

Determining the total area of aphthous lesions through Fiji software

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

##### **Description**

Intervention group: Includes 25 patients selected from the city's pharmacies and randomly selected based on the RND function of Excel software. Patients will use the prepared drug twice a day (0.05% colchicine adhesive mucus gel) at the rate of one drop for each aphthous. At the beginning of treatment and after every 2 to 10 days, the condition of the aphthous lesions is evaluated in terms of pain intensity (score 0 to 4), total lesion area and intensity of redness and inflammation (score 0 to 4) and number of lesions.

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

Control group: Includes 25 patients selected from the city's pharmacies and randomly selected based on the RND function of Excel software. Patients will use one placebo twice a day (base glue-free mucosal gel without colchicine) at the rate of one drop per aphthous. At the beginning of treatment and after every 2 to 10 days, the condition of the aphthous lesions is evaluated in terms of pain intensity (score 0 to 4), total lesion area and intensity of redness and inflammation (score 0 to 4) and number of lesions.

##### **Category**

Placebo

### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Drug stores

###### **Full name of responsible person**

Dr. Mohsen Zabihi

###### **Street address**

Alem sq.

###### **City**

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##### **Province**

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##### **Postal code**

8916978477

##### **Phone**

+98 35 3820 3419

##### **Email**

mzabihi100@gmail.com

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Yazd University of Medical Sciences

###### **Full name of responsible person**

Dr. Masood Mirzaei

###### **Street address**

Bahonar sq.

###### **City**

Yazd

###### **Province**

Yazd

###### **Postal code**

###### **Phone**

+98 35 3726 3733

###### **Email**

dvc.research@ssu.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

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

No

##### **Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

##### **Full name of responsible person**

Dr. Mohsen Zabihi

##### **Position**

Professor

##### **Latest degree**

Ph.D.

##### **Other areas of specialty/work**

Medical Pharmacy

##### **Street address**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

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Dr. Mohsen Zabihi

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**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Zabihi

**Position**

Professor

**Latest degree**

Ph.D.

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**Email**

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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