

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effectiveness of ibuprofen-containing mucoadhesive on minor recurrent aphthous stomatitis

#### Protocol summary

##### Study aim

Determining the effectiveness of ibuprofen-containing mucoadhesive on minor recurrent aphthous stomatitis

##### Design

Controlled clinical trial, with parallel groups, double-blind, randomized, phase 3 on 44 patients, Randomization with random allocation software 2

##### Settings and conduct

Touba Dental Clinic, Mazandaran University of Medical Sciences Intervention method in the intervention group (ibuprofen) and control (placebo): Use of mucosal adhesive 3 times a day for 30 minutes (without eating or drinking during use) (In addition to the examination on the day of visit), the patient must return on the third, fifth and seventh days to check the pain level with a visual analog scale, the size of the wound with a probe In this double-blind study (researcher, analyst and participant) for blinding, codes A (ibuprofen) and B (placebo) will be generated using software. Finally, the codes will be placed in a sealed envelope and the sample number will be written on the envelope. These envelopes, along with the adhesive mucus, will be in dark packaging with the same color and shape.

##### Participants/Inclusion and exclusion criteria

Inclusion: Men and women 18 to 50 years of age; having aphthous ulcers (within 48 hours of lesion formation, with a size smaller than 10 mm); aphthous lesions on the lips and buccal mucosa Exclusion: Pregnancy or lactation; ulcers as a manifestation of a systemic disease; taking nonsteroidal anti-inflammatory drugs, narcotics, immunomodulators, analgesics; people with diseases such as active gastrointestinal or cerebrovascular bleeding, uncontrolled heart failure, lupus, renal failure and liver failure or disease

##### Intervention groups

In the intervention and placebo groups, the medication will be applied 3 times daily (the patient should refrain from eating and drinking for 30 minutes during use).

##### Main outcome variables

Pain level; Ulcer size

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20241208063987N1**

Registration date: **2024-12-24, 1403/10/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-12-24, 1403/10/04**

Update count: **0**

##### Registration date

2024-12-24, 1403/10/04

##### Registrant information

##### Name

Abbas Abbasi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 935 523 6027

##### Email address

abbas.abbasi61@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-12-21, 1403/10/01

##### Expected recruitment end date

2025-03-20, 1403/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Investigating the effectiveness of ibuprofen-containing mucoadhesive on minor recurrent aphthous stomatitis

### Public title

The effect of ibuprofen on aphthous ulcer

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Men and women aged 18 to 50 years who have the ability to follow the doctor's recommendations who are willing to participate in the study and do not use painkillers during it who have a Aphthous ulcer (no more than 48 hours have passed since the lesion formed;) with a size smaller than 10 mm patients who have Aphthous ulcer in the lips and buccal mucosa (due to greater availability and fewer movements, which allow the mucosal adhesive to remain on the lesion)

#### Exclusion criteria:

Due to the possibility of drug interactions, people taking lithium, warfarin, oral hypoglycemic drugs, high-dose methotrexate, antihypertensive drugs, angiotensin-converting enzyme inhibitors, beta-blockers, and diuretics were excluded from the study Pregnancy or breastfeeding Ulcers as a manifestation of a systemic disease such as Behçet's disease, ulcerative colitis, Crohn's disease, or acquired immunodeficiency Use of narcotics, immunomodulating agents, and systemic antibiotics within 2 weeks prior to study entry Treatment with any topical or oral medication within 1 month prior to study entry Invasive dental procedure within 2 weeks prior to study entry A patient who uses toothpaste containing anti-inflammatory drugs People with conditions such as active gastrointestinal or cerebrovascular bleeding, uncontrolled heart failure, lupus, kidney failure, and liver failure or disease

### Age

From **18 years** old to **50 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **44**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In order to allocate the samples to two groups, the random block method will be used. For this purpose, patients will receive numbers 1 to 44. The randomization unit will be individually and according to the number with blocks of 2 people. The selection of the type of group for

each person will be done through random allocation 2 statistical software. Using the software, codes A and B will be generated. Finally, the codes will be placed in a sealed envelope and the sample number will be written on the envelope. After the arrival of each sample, the doctor will test the desired drug, which is placed in dark packages with the same color and shape and is supplied with each envelope on the patient.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Double-blind (i.e., the patient, the data collector (researcher, clinical caregiver and outcome assessor), and the person conducting the statistical analysis are unaware of and blind to the intervention). These people will not know how to distribute the adhesives, and the adhesives will be available to patients in dark packages with the same color and shape.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

##### Street address

Vice Chancellor for Research and Technology of Mazandaran University of Medical Sciences, Moalem Square, Moalem Ave.

##### City

Sari

##### Province

Mazandaran

##### Postal code

4817844718

#### Approval date

2024-10-01, 1403/07/10

#### Ethics committee reference number

IR.MAZUMS.REC.1403.301

## Health conditions studied

### 1

#### Description of health condition studied

Minor recurrent aphthous stomatitis

#### ICD-10 code

K12.0

#### ICD-10 code description

Recurrent oral aphthae

## Primary outcomes

### 1

#### Description

The distance between the 2 outer edges of the ulcer border in mm; lesions less than 1 mm in diameter will be considered healed.

#### Timepoint

The day of referral (starting the use of the drug), the third, fifth and seventh day after that

#### Method of measurement

To determine the wound size, the researcher measures the distance between the 2 outer edges of the wound border in millimeters using a calibrated dental probe (D&G, Pakistan)

### 2

#### Description

Patients are taught to determine the intensity of their pain based on a visual analogue scale. Patients will record their pain in a checklist 3 times a day after each meal and lesions with a pain value of 1 cm or less will be considered healed.

#### Timepoint

3 times a day until the lesion heals

#### Method of measurement

Using a visual analogue scale, so that the patient marks his pain level from 0 to 10 3 times a day after each meal on a 10 cm line.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Use of Ibuprofen Mucoadhesive Gel; Chemical composition: Ethanol 70%(10%w/w), Propyl-paraben (0.02%), Methyl-paraben (0.2%), D-mannitol (7.5%), HPMC k100 (8%), Carbopol 974p (2%), Glycerol (15%), Tween 80 (0.2%), Ibuprofen (5%), Water (Up to 100), Dose: Each application of the gel will deposit approximately 0.5 mg of the drug on the lesion; each dose contains 25 mg of ibuprofen (equivalent to 75 mg 3 times a day), Duration of use: Until the lesion heals (maximum 7 days)

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo; the chemical composition and administration method will be similar to the original drug but without ibuprofen.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Touba dental clinic

##### Full name of responsible person

Abbas Abbasi

##### Street address

Touba dental clinic, Khazar Blvd.

##### City

Sari

##### Province

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##### Postal code

4816895475

##### Phone

+98 11 3340 5474

##### Email

Abbas.abbasi61@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Azam Haddadi

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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

Mazandaran 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

t\_molania117@yahoo.com

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
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Abbas Abbasi  
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Student  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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