

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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		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.	
Scientific title		Blinding (investigator's opinion)	
Investigating the effectiveness of ibuprofen-containing mucoadhesive on minor recurrent aphthous stomatitis		Double blinded	
Public title		Blinding description	
The effect of ibuprofen on aphthous ulcer		Double-blind (i.e., the patient, the data collector (researcher, clinical caregiver and outcome assessor), and the person conducting the statistical analysis is 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.	
Purpose		Placebo	
Treatment		Used	
Inclusion/Exclusion criteria		Assignment	
Inclusion criteria:		Parallel	
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)		Other design features	
Exclusion criteria:		Secondary Ids	
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		empty	
Age		Ethics committees	
From 18 years old to 50 years old		1	
Gender		Ethics committee	
Both		Name of ethics committee	
Phase		Ethics committee of Mazandaran University of Medical Sciences	
3		Street address	
Groups that have been masked		Vice Chancellor for Research and Technology of Mazandaran University of Medical Sciences, Moalem Square, Moalem Ave.	
• Participant • Care provider • Investigator • Outcome assessor • Data analyser		City	
Sample size		Sari	
Target sample size: 44		Province	
Randomization (investigator's opinion)		Mazandaran	
Randomized		Postal code	
Randomization description		4817844718	
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		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

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Mazandaran

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4816895475

Phone

+98 11 3340 5474

Email

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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

Full name of responsible person

Abbas Abbasi

Position

Student

Latest degree

Master

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Tahereh Molania

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Abbas Abbasi

Position

Student

Latest degree

Master

Other areas of specialty/work

Dentistry

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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