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 mucusal 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

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Iran (Islamic Republic of)

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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 mucusal 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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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

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 updating data

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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