

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Investigating the effectiveness of oral allicin tablets on minor recurrent aphthous stomatitis

Protocol summary

Study aim

Determining the effectiveness of oral allicin tablets on minor recurrent aphthous stomatitis

Design

Controlled clinical trial, with parallel groups, unblinded, randomized, phase 3 on 60 patients. Randomization with random allocation software 2

Settings and conduct

Touba Dental Clinic, Mazandaran University of Medical Sciences Intervention method: In the intervention group (with oral allicin tablets) and control (placebo): 4 tablets (every 6 hours) daily (In addition to the examination on the day of referral), the patient must return on the third, seventh, and tenth days to assess the pain level with a visual analog scale, the size of the wound with a probe, and the length of the healing period. In this study, due to the garlic smell of the allicin-containing tablets, blinding will not be performed and the tablets will be provided to the patients after randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women aged 18 to 50 years; patients with aphthous lesions on the lips, buccal mucosa, floor of the mouth and tongue; maximum 48 hours have passed since the lesion formation. Exclusion criteria: Allergy to allicin; pregnancy or lactation; ulcer as a manifestation of a systemic disease such as Behçet's disease, ulcerative colitis, Crohn's disease or acquired immunodeficiency; use of non-steroidal anti-inflammatory drugs, narcotics, immunomodulating agents; systemic antibiotics use in the 2 weeks prior to study entry; the patient has a bleeding disorder

Intervention groups

The intervention group will receive oral allicin tablets (400 mg, Dineh, Iran) containing 1100 micrograms of allicin, and the control group will receive placebo. The patient will take 4 allicin tablets (every 6 hours) (4.4 mg daily) for 10 days.

Main outcome variables

Pain level; Ulcer size; Healing period

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241208063988N1**

Registration date: **2024-12-21, 1403/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2024-12-21, 1403/10/01**

Update count: **0**

Registration date

2024-12-21, 1403/10/01

Registrant information

Name

Behrouz Todarvari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 936 772 6411

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-21, 1403/10/01

Expected recruitment end date

2025-03-21, 1404/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of oral allicin tablets on minor recurrent aphthous stomatitis		groups. The tablets will be provided to the patients with the prior knowledge of the researcher.	
Public title	The effect of oral allicin tablets on aphthous ulcers	Placebo	Used
Purpose	Treatment	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: Patients with minor recurrent aphthous stomatitis Men and women aged 18 to 50 who are able to follow a doctor's advice Willing to participate in the study and not use painkillers during it Patients with aphthous lesions on the lips, buccal mucosa, floor of the mouth, and tongue Has an aphthous ulcer (up to 48 hours have passed since the lesion formed) smaller than 10 mm Exclusion criteria: History of allergy to allicin 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 nonsteroidal anti-inflammatory drugs, narcotics, immunomodulating agents, systemic antibiotics in the 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 The patient has a bleeding disorder.	Other design features	
Age	From 18 years old to 50 years old	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	3	1	
Groups that have been masked	Participant	Ethics committee	
Sample size	Target sample size: 60	Name of ethics committee	Ethics Committee of Mazandaran University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	Vice President for Research and Technology of Mazandaran University of Medical Sciences, Moallem Square, Moallem Ave.
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 60. 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.	City	Sari
Blinding (investigator's opinion)	Single blinded	Province	Mazandaran
Blinding description	In this single-blind study, only the participants will be unaware of the type of drug they are receiving, and the other people involved in the study will be aware of the drug given to the participants (allicin tablets or placebo). Of course, the presence of the therapeutic drug and placebo will be mentioned in the written consent form, and the patient will be aware of the existence of two	Postal code	4817844718
		Approval date	2024-11-13, 1403/08/23
		Ethics committee reference number	IR.MAZUMS.REC.1403.372
		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	Day of referral (start of use), third, seventh, and tenth after starting use
		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

Day of referral (start of use), third, seventh, and tenth after starting use

Method of measurement

Using a visual analog scale; in which the patient marks their pain level from 0 to 10 on a 10-centimeter line on the day of the visit, third, seventh, and tenth day.

3

Description

Healing period

Timepoint

Day of referral (start of use), third, seventh, and tenth after starting use

Method of measurement

If both the pain level on the visual analog scale is 1 cm or less and the lesion size is 1 mm or less, the lesion is considered healed.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive oral allicin tablets (400 mg, Dineh, Iran) containing 1100 micrograms of allicin. The patient will take 4 allicin tablets daily (every 6 hours) (4.4 mg daily) for 10 days.

Category

Treatment - Drugs

2

Description

Control group: It will be similar to oral allicin tablets but without allicin; 4 time a day (every 6 hours) for 10 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Touba dental clinic

Full name of responsible person

Behrouz Tadarvari

Street address

Touba dental clinic, Khazar Blvd.

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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

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Behrouz Tadarvari

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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

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Student

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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