Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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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

Public title
The effect of oral allicin tablets on aphthous ulcers
Purpose
Treatment
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.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
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 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.
Blinding (investigator's opinion)
Single blinded
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 groups. The tablets will be provided to the patients with the prior knowledge of the researcher.
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 President for Research and Technology of Mazandaran University of Medical Sciences, Moallem Square, Moallem Ave.
City
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Province
Mazandaran
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 Todarvari
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Sponsors / Funding sources

1

Sponsor
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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 Todarvari
Position
Student
Latest degree
A Level or less

Other areas of specialty/work
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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