Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Therapeutic effects of Zataria Multiflora Essential Oil on recurrent oral aphthous lesions

Protocol summary

Summary

Aims: Aphthous lesions are one of the most common diseases of the oral cavity. They can cause severe pain, and there is no definite cure. The purpose of this study was to determine the efficacy of Zataria multiflora (ZM, a thyme-like plant) essential oil for the control and treatment of aphthous lesions. Design: This study was triple blind clinical trial. Participants: This study was performed on 28 patients who were randomly selected from all patients suffering from recurrent aphthous lesions who were admitted to the Department of Oral Medicine, Faculty of Dentistry, Babol University of Medical Sciences in the north of Iran. The patients were divided into ZM- and placebo-treated groups. Inclusion criteria were as follows: 1) Presence of a minor solitary aphthous lesion in labial or buccal epithelium. 2) No usage of other treatments for aphthous lesions. 3) No reduction in pain, pain intensity or burning sensation at the time of admission compared to the first days of occurrence of the lesion. 4) Willingness to participate in the study. 5) Age between 18 and 40 years. Patients were excluded from the study: with any systemic diseases ,pregnant patients; those with aphthous lesions older than 4 days and those who declined entering the study. How to study: Patient were divided into two groups (eight men and six women in each group) and given ZM or placebo (control). The healing time, pain intensity and aphthous zone diameter were recorded for each patient. Data were analyzed using Mann-Whitney and Friedman tests. Interventions: The patients received a bottle of 0.5% ZM essential oil or a bottle of placebo (distilled water with a cap scented with ZM essential oil). Standard ZM essence was obtained from Barij Essence Pharmaceutical Company (Kashan, Iran). Major outcome measure: Therapeutic effects of Zataria Multiflora Essential Oil on recurrent oral aphthous lesion that The pain intensity was measured using a VAS (visual analog scale), which the patients completed every day for 10 days (before and after treatment).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408076926N2**
Registration date: **2014-08-28, 1393/06/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-08-28, 1393/06/06

Registrant information

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2012-05-28, 1391/03/08

Expected recruitment end date

2013-06-25, 1392/04/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Therapeutic effects of Zataria Multiflora Essential Oil on recurrent oral aphthous lesions

Public title
Therapeutic effects of Zataria Multiflora Essential Oil on recurrent oral aphthous lesions

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria were as follows: 1) Presence of a minor solitary aphthous lesion in labial or buccal epithelium. 2) No usage of other treatments for aphthous lesions. 3) No reduction in pain, pain intensity or burning sensation at the time of admission compared to the first days of occurrence of the lesion. 4) Willingness to participate in the study. 5) Age between 18 and 40 years old. Patients were excluded from the study: with any systemic diseases; pregnant patients; those with aphthous lesions older than 4 days and those who declined entering the study.

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Babol University of Medical Sciences

Street address
Babol University of Medical Sciences

City
Babol

Postal code

Approval date
2011-09-23, 1390/07/01

Ethics committee reference number
5467

Health conditions studied

1

Description of health condition studied
Recurrent oral aphthous lesions

ICD-10 code
K12.0

ICD-10 code description
Recurrent oral aphthae

Primary outcomes

1

Description
Recurrent oral aphthous lesion

Timepoint
Days: 0, 5, 7 and 10

Method of measurement
The healing time, pain intensity and aphthous zone diameter

Secondary outcomes

1

Description
Pain

Timepoint
Days: 0, 5, 7 and 10

Method of measurement
Visual analog scale

Intervention groups

1

Description
in intervention group:a bottle of 0.5% ZM essential oil

Category
Treatment - Drugs

2

Description
interventon in control group: a bottle of placebo (distilled water with a cap scented with ZM essential oil)

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Oral Medicine, Faculty of Dentistry, Babol University of Medical Sciences

Full name of responsible person
Dr. Neda Babaee
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Sponsors / Funding sources

1

Sponsor
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Babol University of Medical Sciences
Full name of responsible person
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City
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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
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty