

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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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Name of organization / entity

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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

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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 Babaei

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Faculty of Dentistry, Babol University of Medical Sciences

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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****Contact****Name of organization / entity**

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Web page address**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