

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Evaluation of the effectiveness of *Boswellia serrata* extract (frankincense) in the treatment of oral aphthous ulcers compared to placebo

Protocol summary

Study aim

Evaluation of the clinical effectiveness of frankincense extract in the treatment of oral aphthous ulcers

Design

Two arm parallel group randomized placebo-controlled clinical trial, phase 3 on 50 patients. Block randomization method with blocks of 4 was used for randomization.

Settings and conduct

The study was performed at the dental clinic of Isfahan University of Medical Sciences. The subjects in experimental and control groups were instructed to use *Boswellia* and placebo orally disintegration tablets (ODTs), respectively, 4 times daily for 3 days. The severity of pain and size of the ulcer before the intervention (day 0) and at the beginning of the second and fourth days (end of treatment) were recorded for each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age of 18 years or more 2. Having 1 to 5 oral aphthous ulcers 3. No more than 48 hours of aphthous occurrence Exclusion criteria: 1. Underlying aphthous ulcer-inducing disease 2. Pregnancy 3. Lactation 4. Receiving any anti-inflammatory or immunosuppressive drug within the last 2 weeks 5. Receiving any systemic antibiotic within the last 2 weeks 6. Treatment of aphthous ulcer with any other drug within recent 3 days

Intervention groups

Experimental group: orally disintegrating tablets of frankincense extract (manufactured by the faculty of Pharmacy) standardized based on 5.90% w/w of 11-keto-beta-boswellic acid, 4 times daily Control group: orally disintegrating tablets of placebo (manufactured by the faculty of Pharmacy), 4 times daily

Main outcome variables

Ulcer size; Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023282N10**

Registration date: **2020-04-25, 1399/02/06**

Registration timing: **retrospective**

Last update: **2020-04-25, 1399/02/06**

Update count: **0**

Registration date

2020-04-25, 1399/02/06

Registrant information

Name

Rasool Soltani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

2017-12-22, 1396/10/01

Actual recruitment end date

2018-08-21, 1397/05/30

Trial completion date

2018-08-21, 1397/05/30

Scientific title

Evaluation of the effectiveness of Boswellia serrata extract (frankincense) in the treatment of oral aphthous ulcers compared to placebo

Public title

The effectiveness of frankincense in the treatment of oral aphthae

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 years or more Having 1 to 5 oral aphthous ulcers No more than 48 hours of aphthous occurrence; Not receiving any systemic antibiotic within the last 2 weeks

Exclusion criteria:

Pregnancy Lactation Underlying disease causing oral aphthous ulcer

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method was used in which blocks of 4 were used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drug (frankincense) and placebo tablets will be fully similar and packaged in similar containers. The patient, the prescriber (physician), data analyst, and the laboratory personnel will be blind to the content of containers and intervention type.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Vice-chancellery for research, Isfahan University of Medical Sciences, Hezar-Jerib Ave., Isfahan

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Isfahan

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8174673461

Approval date

2017-11-26, 1396/09/05

Ethics committee reference number

IR.MUI.REC.1396.3.572

Health conditions studied

1

Description of health condition studied

Oral aphthous ulcer

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

Oral aphthous ulcer size

Timepoint

Before the intervention, 2 and 4 days after the start of intervention

Method of measurement

Dental caliper

2

Description

Ulcer pain severity

Timepoint

Before the intervention, 2 and 4 days after the start of intervention

Method of measurement

Visual analogue scale (VAS)

Secondary outcomes

1

Description

The number of cases with complete ulcer healing

Timepoint

End of ontervention (4th day)

Method of measurement

Observation

Intervention groups**1****Description**

Intervention group: orally disintegrating tablets of frankincense extract (manufactured by the faculty of Pharmacy) standardized based on 5.90% w/w of 11-keto-beta-boswellic acid, 4 times daily

Category

Treatment - Drugs

2**Description**

Control group: orally disintegrating tablets of placebo (manufactured by the faculty of Pharmacy), 4 times daily

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dental Clinic of Isfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

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Faculty of Dentistry, Isfahan University of Medical Sciences, Soffeh Avenue

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

Esfahan 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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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

Esfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

Position

Associate professor

Latest degree

Specialist

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more data.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available