Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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. Rreceiving 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)

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+98 31 3792 7067

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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

City
Isfahan

Province
Isfehan

Postal code
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Assiciate professor
Latest degree
Specialist
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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