Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of Elaeagnus angustifolia extract mucoadhesive buccal film in the treatment of oral recurrent aphthous ulcers: a randomized single-blind placebo-controlled clinical trial

Protocol summary

Study aim
Evaluation of the clinical effectiveness of Elaeagnus angustifolia extract mucoadhesive buccal film in the treatment of oral recurrent aphthous ulcers

Design
Two arm parallel group randomized placebo-controlled clinical trial, phase 3 on 34 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 Elaeagnus angustifolia extract and placebo mucoadhesive buccal film, respectively, 4 times daily for 4 days. The severity of pain and size of the ulcer before the intervention (day 0) and at the beginning of the third and fifth 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: mucoadhesive buccal film of Elaeagnus angustifolia extract (manufactured by the faculty of Pharmacy) standardized based on total phenol count(TPC), 4 times daily for 4 days. Control group: mucoadhesive buccal film of placebo (manufactured by the faculty of Pharmacy), 4 times daily for 4 days.

Main outcome variables
Ulcer size; pain severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150721023282N27**
Registration date: **2024-02-17, 1402/11/28**
Registration timing: **prospective**

Last update: **2024-02-17, 1402/11/28**
Update count: **0**

Registration date
2024-02-17, 1402/11/28

Registrant information

Name
Rasool Soltani

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2024-09-20, 1403/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effectiveness of Elaeagnus angustifolia extract mucoadhesive buccal film in the treatment of oral recurrent aphthous ulcers: a randomized single-blind placebo-controlled clinical trial

Public title
The effectiveness of russian olive 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
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method will be used using blocks of 4. For this, all cases of quadruple arrangement (including two drugs and two placebos) in a block will be designed and a code will be given to each block. The blocks will be selected using a random number table and patients are assigned to each of the two groups based on the order of the selected block.

Blinding (investigator's opinion)
Double blinded

Blinding description
Drug (Elaeagnus angustifolia extract) and placebo mucoadhesie buccal film will be fully similar and packaged in similar containers. The prescriber (physician) and the data analyst 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
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Vice-chancellery for research, Isfahan University of Medical Sciences, Hezar-Jerib Ave., Isfahan
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8174673461

Approval date
2023-10-25, 1402/08/03

Ethics committee reference number
IR.MUI.PHANUT.REC.1402.029

Health conditions studied

1

Description of health condition studied
Oral recurrent aphthous ulcer

ICD-10 code
Recurrent

ICD-10 code description
K12.0

Primary outcomes

1

Description
Oral aphthous ulcer size

Timepoint
Before the intervention, 2 and 5 days after the start of intervention

Method of measurement
Dental caliper

2

Description
Pain severity

Timepoint
Before the intervention, 2 and 5 days after the start of intervention

Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
The number of cases with complete ulcer healing
Timepoint
End of ontervention (5th day)
Method of measurement
Observation

Intervention groups

1

Description
Intervention group: mucoadhesive buccal film of Elaeagnus angustifolia extract (manufactured by the faculty of Pharmacy) standardized based on total phenol count(TPC), 4 times daily for 4 days
Category
Treatment - Drugs

2

Description
Control group: mucoadhesive buccal film 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
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Sponsors / Funding sources

1

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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
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Esfahan University of Medical Sciences
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Rasool Soltani
Position
professor
Latest degree
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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