

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 31 3792 7067

Email address

soltani@pharm.mui.ac.ir

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 mucoadhesive 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

Street address

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

City

Isfahan

Province

Isfahan

Postal code

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

Rasool Soltani

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3303 3950

Email

soltani@pharm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Isfahan University of Medical Sciences, Hezar-Jerib Avenue

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

sh_haghjoo@med.mui.ac.ir

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

professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Faculty of Pharmacy, Isfahan University of Medical Sciences, Hezar-Jerib Avenue

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7067

Email

soltani@pharm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Department of Clinical Pharmacy, Faculty of Pharmacy, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7067

Email

soltani@pharm.mui.ac.ir

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

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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