

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The efficacy of Rosa damascena extract in the treatment of recurrent aphthous stomatitis: A randomized parallel controlled trial

Protocol summary

Summary

Recurrent aphthous stomatitis (RAS) is a condition which is marked by painful ulcers that develop on non-keratinized oral mucosa. This condition can cause problems with swallowing, eating and speaking. Extract of rosa damascena has reportedly anti-inflammatory effects and has been traditionally used by some cultures for the treatment of oral ulcers. The aim of the present randomized, double-blind, placebo controlled investigation is to assess the clinical efficacy of a mouthwash containing aqueous extract of rosa damascena in the treatment of RAS. Patients with at least one aphthous ulcer measuring no more than 10 mm in diameter with no underlying systemic or immunologic disease will be included. Patients will randomly enter this 2 week study and the clinical efficacy of the mouthwash on size, pain and number of ulcers will be compared with that of the placebo on days 4,7,11 and 14. Both groups (experimental and placebo) will be instructed to rinse the given mouthwash four times per day preferably after oral hygiene. The examinations will be performed by one calibrated clinician.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811063182N1**

Registration date: **2010-06-06, 1389/03/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-06, 1389/03/16

Registrant information

Name

Keyvan Sohrabi Anaraki

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2008-02-10, 1386/11/21

Expected recruitment end date

2010-01-01, 1388/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Rosa damascena extract in the treatment of recurrent aphthous stomatitis: A randomized parallel controlled trial

Public title

The efficacy of Rosa damascena extract in the treatment of recurrent aphthous stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The presence of at least one aphthous ulcer measuring no more than 10 mm in diameter (formation no more than 48h), had no underlying systemic or immunologic disease such as rheumatoid arthritis and behcet syndrome. Patients were excluded if

they had used NSAIDs, corticosteroids or other immunoregulatory agents within 1 month prior to the study or were less than 18 years of age.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences

City

Mashhad

Postal code

Approval date

2008-12-30, 1387/10/10

Ethics committee reference number

87464

Health conditions studied

1

Description of health condition studied

Recurrent aphthous stomatitis

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

Change in Ulcer Size (mm²)

Timepoint

on day 0 (baseline), days 4, 7, 11 and 14

Method of measurement

Ulcer size is measured by one examiner with the use of a calibrated dental probe with millimeter markings.

2

Description

Change in number of Aphthae

Timepoint

on day 0 (baseline), days 4, 7, 11 and 14

Method of measurement

Only ulcers which would come into contact with the rinse (i.e. in the oral cavity) will be considered.

3

Description

Change in Pain

Timepoint

on day 0 (baseline), days 4, 7, 11 and 14

Method of measurement

the Perceived Pain Rating Scale as introduced by Barker et al, 1991

Secondary outcomes

empty

Intervention groups

1

Description

Placebo

Category

Placebo

2

Description

Rosa damascena extract 20%, 4 times per day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Mashhad University of Medical Sciences

Full name of responsible person

Dr H.Hoseinpour

Street address

Vakil abad Ave, Oral Medicine Department

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of
Medical Sciences

Full name of responsible person

Dr Tavakol Afshari

Street address

Daneshgah St.

City

Mashhad

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Keyvan Sohrabi

Position

DDS/Dentistry

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Dr H.Hoseinpour

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Associate professor / DDS, MS

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Person responsible for updating data

Contact

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