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)

Phone

+98 51 1882 9501

Email address

sohrabiak831@mums.ac.ir

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 Apthae

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 Medcine 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
Mashahd University of Medical Sciences
Full name of responsible person
Keyvan Sohrabi
Position
DDS/Dentistry
Other areas of specialty/work
Street address
School of Dentistry
City
Mashhad
Postal code
91735
Phone
+98 51 1882 9501
Fax
Email
k1sohrabi@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad university of medical sciences
Full name of responsible person
Dr H.Hoseinpour
Position
Associate professor / DDS, MS
Other areas of specialty/work
Street address
School of dentistry, Departement of oral medicine
City
Mashhad
Postal code
91735
Phone
+98 51 1882 9501
Fax
Email
HoseinpourH@mums.ac.ir
Web page address

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