

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Designing and fabricating oral Bioadhesive from Onosma Bulbotricum and study of its therapeutic effect on the patient with Recurrent Aphthous Stomatitis (RAS)

Protocol summary

Study aim

Designing and fabricating oral Bioadhesive from Onosma Bulbotricum and study of its therapeutic effect on the patient with Recurrent Aphthous Stomatitis (RAS)

Design

This study is a non-blinded clinical trial. The research population will be included all patients referring to Kermanshah Dental School. 120 eligible patients will be selected conveniently and randomly will be assigned to two intervention and control groups.

Settings and conduct

This study that will be conducted in Dental School of Kermanshah is a non-blinded one. Patients in both intervention and control groups are visited after starting treatment every other day for one week

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aphthous stomatitis occurs at least three times a year; Age between 18 and 60 years
Exclusion criteria: pregnant women

Intervention groups

The intervention group will receive oral Bioadhesive extracted from Onosma Bulbotricum (from borage species) topically for 3 days (several times a day) for a week. The control group will receive 1% triamcinolone topical gel (with trademarked of Teriident) three days a week (several times a day) for one week.

Main outcome variables

Pain, number of oral lesions, average diameter of oral lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N150**
Registration date: **2020-05-26, 1399/03/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-26, 1399/03/06**

Update count: **0**

Registration date

2020-05-26, 1399/03/06

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing and fabricating oral Bioadhesive from Onosma Bulbotricum and study of its therapeutic effect on the patient with Recurrent Aphthous Stomatitis (RAS)

Public title

Designing and fabricating oral Bioadhesive from Onosma Bulbotricum and study of its therapeutic effect on the patient with Recurrent Aphthous Stomatitis (RAS)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aphthous stomatitis occurs at least three times a year

Age between 18 and 60 years

Exclusion criteria:

pregnant women

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random number table. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-02-04, 1398/11/15

Ethics committee reference number

IR.KUMS.REC.1398.1150

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

Pain

Timepoint

The second day after starting treatment as every other day for one week

Method of measurement

Based on a visual pain scale (VAS)

2

Description

number of oral lesions

Timepoint

The second day after starting treatment as every other day for one week

Method of measurement

By a specialist in oral, maxillofacial and facial diseases

3

Description

the average diameter of oral lesions

Timepoint

The second day after starting treatment as every other day for one week

Method of measurement

Using a ruler

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive oral Bioadhesive extracted from Onosma Bulbotricum (from borage species) topically for 3 days (several times a day) for a week.

Category

Treatment - Drugs

2

Description

The control group will receive 1% triamcinolone topical gel (with trademarked of Teriident) three days a week (several times a day) for one week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry

Full name of responsible person

Dr. Masoome Eivazi

Street address

Shariati Ave, Faculty of Dentistry

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6713954658

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+98 83 3729 6591

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masoomeeivazi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

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fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Tahvilian

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Kermanshah University of Medical Sciences

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Dr. Masoome Eivazi

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

Send E-mail to the responsible for the update to get the documentation

What processes are involved for a request to access data/document

Documentation will be emailed within a 15-day timeframe

Comments