

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Preparation and clinical trial of Mucoadhesive Polymeric Gel Containing Syzygiumaromaticum, Glycyrrhizaglabra, Punicagranatum L. Extract for Treatment of Oral Aphthae

Protocol summary

Study aim

Preparation and clinical trial of Mucoadhesive Polymeric Gel Containing Syzygiumaromaticum, Glycyrrhizaglabra, Punicagranatum L. Extract for Treatment of Oral Aphthae

Design

patients with aphthous ulcers with at least 5 years old

Settings and conduct

Faculty of pharmacy. Zanzan university of medical sciences

Participants/Inclusion and exclusion criteria

patients with aphthous ulcers with at least 5 years old

Intervention groups

Description: Placebo group: 20 patients with oral aphthous, receiving placebo gel , three times a day, after breakfast and lunch and before sleeping at night, for 7 days Category: Placebo Description: Intervention group: 20 patients with oral aphthous, receiving medical gel (Mucoadhesive Gel Containing Syzygium aromaticum, Glycyrrhiza glabra, Punica granatum L. Extract), three times a day, after breakfast and lunch and before sleeping at night, for 7days Category: Treatment - Drugs

Main outcome variables

Primary outcomes Description:The amount of oral aphthous resized in response to treatment with medical gel (Mucoadhesive Gel Containing Syzygium aromaticum, Glycyrrhiza glabra, Punica granatum L. Extract) Timepoint: In the first visit and after 2,4 and 7 days next Method of measurement: With colis the largest diameter of the oral aphthous is measured and anatomical position is recorded Secondary outcomes Description:Pain score during the treatment Timepoint: At the first session of treatment, 2 ,4 and7 days next Method of measurement:A score 0 to 10 will be given by the patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220731055591N1**

Registration date: **2022-11-02, 1401/08/11**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-02, 1401/08/11**

Update count: **0**

Registration date

2022-11-02, 1401/08/11

Registrant information

Name

Alireza Yazdinezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 8713

Email address

yazd1387@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-13, 1401/05/22

Expected recruitment end date

2023-11-13, 1402/08/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preparation and clinical trial of Mucoadhesive Polymeric Gel Containing Syzygiumaromaticum, Glycyrrhizaglabra, Punicagranatum L. Extract for Treatment of Oral Aphthae

Public title

Preparation and clinical trial of Mucoadhesive Polymeric Gel Containing Syzygiumaromaticum, Glycyrrhizaglabra, Punicagranatum L. Extract for Treatment of Oral Aphthae

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with aphthous ulcers with at least 5 years old

Exclusion criteria:

patients with immunodeficiency disorders

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: 20

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

The samples were given to the treating physician with a code (code A: Mucoadhesive Polymeric Gel Containing Syzygium aromaticum, Glycyrrhiza glabra, Punica granatum L. Extract and code B: Mucoadhesive Polymeric Gel without Syzygium aromaticum, Glycyrrhiza glabra, Punica granatum L. Extract) , and patients are not aware of the contents of the samples.

Placebo

Used

Assignment

Parallel

Other design features

no

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Zanjan University of Medical Sciences

Street address

Gavazang Blvd.

City

Zanjan

Province

Zanjan

Postal code

4513983153

Approval date

2022-06-21, 1401/03/31

Ethics committee reference number

IR.ZUMS.REC.1401.139

Health conditions studied

1

Description of health condition studied

oral aphthae

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

Recurrent oral aphthae with at lest 2 mm diameter

Timepoint

every 1 day

Method of measurement

diameter of oral aphthae (mm)

Secondary outcomes

empty

Intervention groups

1

Description

Placebo group: 20 patients with oral aphthous, receiving placebo gel , three times a day, after breakfast and lunch and before sleeping at night, for 7 days

Category

Treatment - Drugs

2

Description

Intervention group: 20 patients with oral aphthous, receiving medical gel (Mucoadhesive Gel Containing Syzygium aromaticum, Glycyrrhiza glabra, Punica granatum L. Extract), three times a day, after breakfast and lunch and before sleeping at night, for 7days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan Faculty of Dentistry

Full name of responsible person

Mahsa Alavi Namvar

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Faculty of Dentistry, Zanjan University of Medical Sciences, Gavazang Blvd.

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Email

Mahsa.Alavinamvar@Gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Samad Nadri

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Faculty of Pharmacy, Zanjan University of Medical Sciences, Gavazang Blvd.

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Nadri_s@zums.ac.ir

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

Yes

Title of funding source

Zanjan 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**

Zanjan University of Medical Sciences

Full name of responsible person

Faramarz Dobakhti

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

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