Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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. Zanjan 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

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

City
Zanjan

Province
Zanjan

Postal code
4513983153

Phone
+98 24 3301 8623

Fax
+98 24 3301 8624

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

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

City
Zanjan

Province
Zanjan

Postal code
4513983153

Phone
+98 24 3301 8624

Email
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

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

City
Zanjan

Province
Zanjan

Postal code
4513983153

Phone
+98 24 3301 8624

Email
Fdobakhti@zums.ac.ir

Person responsible for scientific 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
Pharmaciutics

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

City
Zanjan

Province
Zanjan

Postal code
4513983153

Phone
+98 24 3301 8624

Email
Fdobakhti@zums.ac.ir

Person responsible for updating data

Contact

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Zanjan University of Medical Sciences

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Faramarz Dobakhti

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Province
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4513983153
Phone
+98 24 3301 8624
Email
Fdobakhti@zums.ac.ir

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