Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparison between the effectiveness of two different oral pastes, containing Triamcinolone and Rhus Coriaria on patients with minor oral aphthous lesions: a triple blind randomized clinical trial

Protocol summary

Study aim

Determining the effectiveness of two types of oral pastes containing sumac extract and triamcinolone on aphthous ulcers Using herbal medicines (Rhus Coriaria extraction) with less side effects to heal aphthous lesions. Study the effect of medicine on size, pain and duration of lesion healing.

Design

A triple blind randomized clinical trial has three groups; control, intervention and placebo, third phase on 60 patients, using Balance block randomization

Settings and conduct

Patients who referred to Qazvin Dental School during the first 24 hours of the lesion were examined by two oral medicine specialists and after confirmation of aphthous lesions, and after being informed and receiving consent, they entered one of the three groups completely randomly. The containers will be exactly the same and coded and given to the patient randomly by the secretary, the examiner and the patient will be unaware of the contents of the medicine.

Participants/Inclusion and exclusion criteria

Inclusion criteria; No systemic disease (Hypertension, Diabetes, Hyperlipidemic, Bechet's disease, Rheumatoid disease) Do not use medicines, cigarettes', alcohol and addiction. No-entry criteria; Ora ulcers that are not aphthous lesions. More than 48hrs passed from incidence of lesion. Use of medicines, cigarettes', alcohol and addiction. Systemic diseases. Allergic to herbal medicines

Intervention groups

Frist group (control group); Using oral paste containing triamcinolone, Second group (Intervention group); oral paste containing sumac extract, Third group (placebo group); placebo oral paste (without active substance)

Main outcome variables

Size, pain and healing duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210513051281N1**
Registration date: **2021-09-17, 1400/06/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-17, 1400/06/26**
Update count: **0**

Registration date

2021-09-17, 1400/06/26

Registrant information

Name

Zeinab Rezvani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-30, 1400/06/08

Expected recruitment end date

2021-09-30, 1400/07/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A comparison between the effectiveness of two different oral pastes, containing Triamcinolone and Rhus Coriaria on patients with minor oral aphthous lesions: a triple blind randomized clinical trial

Public title
A comparison between the effectiveness of two different oral pastes, containing Triamcinolone and Rhus Coriaria on minor aphthous lesions: a triple blind randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients with minor aphthous lesions who have visited within the first 24 hours of incidence of the lesion. Patient does not have any systemic disease (Hypertension, Diabetes, Hyperlipidemic, Bechet's disease, Rheumatoid disease) Do not use medicines, cigarettes', alcohol and addiction.

Exclusion criteria:
Patients allergic to herbal medicines Oral ulcers that are not aphthous lesions. More than 48hrs passed from incidence of the lesion. Use of medicines, cigarettes', alcohol and addiction. Systemic diseases.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into three treatment groups A, B, C using the Balance block randomization method, the size of each block is 6 and the total number of blocks is 10. Balanced randomization allocation method for participants, in a randomized clinical trial study of the effect of Oral paste, containing Triamcinolone (group A), placebo (group B) and Sumac (group C) in reducing the size, pain and healing duration of the lesion. Randomization unit: individual Randomization tool: based on statistical software

Blinding (investigator's opinion)
Triple blinded

Blinding description
These patients are divided into three groups of triamcinolone, sumac and placebo (10 blocks of 6) based on random allocation. Patients in the first group are given triamcinolone under the brand name Triadent 10 grams (from Raha Daroo Company) three times a day, the second group is given an oral paste containing sumac and the third group is given a placebo. The containers in which the drugs are placed are very similar to each other and the contents are uknown. This study is triple blind. The patient, researcher and statistician are unaware of the type of drug which is given.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qazvin university of medical science

Street address
Qazvin university of medical science, Bahonar Blvd, Qazvin

City
Qazvin

Province
Qazvin

Postal code
3419915315

Approval date
2021-08-30, 1400/06/08

Ethics committee reference number
IR.QUMS.REC.1400.245

Health conditions studied

1

Description of health condition studied
Recurrent Oral aphthae

ICD-10 code
K12.0

ICD-10 code description
Recurrent oral aphthae

Primary outcomes

1

Description
Size

Timepoint
First day, third day, fifth day and seventh day after they start taking the medicine.

Method of measurement
dental probe instrument

2

Description
pain
Timepoint
First day, third day, fifth day and seventh day after they start taking the medicine.
Method of measurement
On study days, the patient is asked to mark from zero to ten on visual analog scale(VAS).

3

Description
healing duration
Timepoint
First day, third day, fifith day and seventh day after they start taking the medicine.
Method of measurement
visual examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the intervention group receive a drug containing the sumac (Rhus Coriaria) active ingredient. They should apply the gel on the aphthous lesion 3 times a day after brushing and avoid eating and drinking for half an hour after that. The drug consists of the sumac (Rhus Coriaria) active ingredient and carboxymethyl cellulose (CMC) with a concentration of 5% of the active ingredient.
Category
Treatment - Drugs

2

Description
Control group: Triamcinolone (Triadent 0.1%) is used as standard treatment. They should apply the oral paste on the aphthous lesion 3 times a day after brushing and avoid eating and drinking for half an hour after that.
Category
Treatment - Drugs

3

Description
Control group: This group receives a placebo (drug without active ingredient). The placebo consists of carboxymethyl cellulose (CMC) only. They should apply the oral paste on the aphthous lesion 3 times a day after brushing and avoid eating and drinking for half an hour after that.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin dental school
Full name of responsible person
Dr Mahdie Zarabadipour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Doctor Seyed Mehdi Mirhashemi
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Dept of research of Qazvin University of Medical Sciences, Shahid Beheshti blvd, Ave 3415613911
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Dr Mahdie Zarabadipour
Position
associate professor
Latest degree
Specialist
Other areas of specialty/work
oral and maxillofacial medicine specialist
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Person responsible for updating data

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Web page address
http://sd.qums.ac.ir/Portal/Home/

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