

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jul 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)

##### Phone

+98 28 3333 6001

##### Email address

n.rezvani96@gmail.com

##### 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 unknown. 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

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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, fifth 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

#### **Street address**

Qazvin dental school, Bahonar Blvd

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#### **Postal code**

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#### **Phone**

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#### **Email**

mzarabadipour@qums.ac.ir

#### **Web page address**

<http://sd.qums.ac.ir/Portal/Home/>

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Qazvin University of Medical Sciences

#### **Full name of responsible person**

Doctor Seyed Mehdi Mirhashemi

#### **Street address**

Dept of research of Qazvin University of Medical Sciences, Shahid Beheshti blvd, Ave 3415613911 Qazvin

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#### **Email**

research.dpt@qums.ac.ir

#### **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

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**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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Qazvin University of Medical Sciences

**Full name of responsible person**

Dr Mahdie Zarabadipour

**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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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