

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparative effects of saliva officinalis gel (salvizan) and triamcinolone asetonide gel in recurrent aphthous stomatitis.

#### Protocol summary

##### Study aim

Comparative effects of Saliva officinalis gel (Salvizan) and Triamcinolone asetonide gel in recurrent aphthous stomatitis.

##### Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients, a random number lottery was used for randomization.

##### Settings and conduct

The study site was the Department of Oral Diseases, School of Dentistry, Isfahan University of Medical Sciences. Sixty patients with recurrent aphthous stomatitis will be given triamcinolone gel to half of the patients and Salvizan gel to the other half until the patients recover. Pain is assessed on days 0, 1, 3, and 5 using the VAS system. This study is performed in a double-blind manner. The participant and the researcher in this study are blind, so that the drugs are poured into the same tubes by a third person and one group is given code A and the other group is given code B. At home, the patient applies one centimeter of gel to the lesion three times a day for complete recovery.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with minor aphthous ulcers  
Have not taken any medication  
Do not have any systemic disease  
No entry criteria : pregnant and lactating people  
Sensitivity to herbal products

##### Intervention groups

Control group : Teriident drug, three times a day, until the wound is completely healed  
Intervention group :  
Salvizan gel, three times a day, until the wound is completely healed

##### Main outcome variables

Pain ; Duration of pain relief; Wound healing time

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20100202003251N7**

Registration date: **2021-10-13, 1400/07/21**

Registration timing: **retrospective**

Last update: **2021-10-13, 1400/07/21**

Update count: **0**

##### Registration date

2021-10-13, 1400/07/21

#### Registrant information

##### Name

Atefeh Tavangar

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1792 2814

##### Email address

tavangar@dnt.mui.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

##### Expected recruitment start date

2021-03-24, 1400/01/04

##### Expected recruitment end date

2021-09-26, 1400/07/04

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Comparative effects of saliva officinalis gel (salvizan) and triamcinolone asetonide gel in recurrent aphthous stomatitis.

## Public title

Evaluation of the effect of salvizan gel on aphthous stomatitis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Minimum age 18 years Non-pregnant and non-breastfeeding women The patient's ability to stay on during the study period.

### Exclusion criteria:

Pregnancy Breastfeeding women People who are sensitive to herbal products Systemic patients such as:, patients with primary or acquired immunodeficiency Patients with a history of taking anti-inflammatory drugs and corticosteroids Major aphthous ulcers and Herpetiform Wounds with durability longer than 48 hours

## Age

From **18 years** old to **50 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random Allocation Law : For this purpose, first determine a total sample volume, then randomly assign a set of them to group A and the rest to group B. In this study, with a sample size of 60 drugs, 30 drugs for intervention group A and 30 drugs for intervention group B are placed in a lottery container and then the drugs are randomly removed from the container without replacement and the sequence created is recorded.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The drugs are placed in the same tubes in terms of sex, color and size and are divided into two codes A and B. However, the patient and the clinician do not know the nature of the drugs and the study is completely double-blind.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Hezar Jerib S, Isfahan University of Medical Sciences

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2021-03-16, 1399/12/26

#### Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.834

## Health conditions studied

### 1

#### Description of health condition studied

Aphthous stomatitis

#### ICD-10 code

K12.0

#### ICD-10 code description

Recurrent oral aphthae

## Primary outcomes

### 1

#### Description

Size of wound

#### Timepoint

The first, third and fifth days after the intervention

#### Method of measurement

Ruler

### 2

#### Description

Pain

#### Timepoint

Before the study, the first, third and fifth days after the start of the study

#### Method of measurement

Visual Analogue Scale

### 3

#### Description

Healing ulcer

#### Timepoint

Before start and after end of the study

#### Method of measurement

Examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: Triadent 0.1%, one centimeter of gel three times a day, until complete healing of wounds and pain on days 0, 1, 3 and 5 marked in the VAS (Visual Analogue Scale) questionnaire Be, abandon the pharmaceutical company

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Salvizan 0.1%, one centimeter of gel three times a day, until complete healing of wounds and their pain on days 0, 1, 3 and 5 marked in the VAS (Visual Analogue Scale) questionnaire Be, Gol Daroo Pharmaceutical Company

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dentistry school of Isfahan University of Medical Science

##### Full name of responsible person

Atefeh Tavangar

##### Street address

Hezar Jerib Street, Isfahan University of Medical Science, Dentistry school

##### City

Isfahan

##### Province

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##### Postal code

8174673461

##### Phone

+98 31 3792 5514

##### Email

tavangar@dnt.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjoo

##### Street address

Hezar Jerib Street, Isfahan University of Medical Science, Dentistry school

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8174673461

##### Phone

+98 31 3668 7898

##### Email

tavangar@dnt.mui.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Atefeh Tavangar

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

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## Person responsible for scientific inquiries

#### Contact

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Esfahan University of Medical Sciences

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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**

Not applicable

**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