

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 : Teriadem 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

Isfahan

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

City

Isfahan

Province

Isfahan

Postal code

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

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5514

Email

tavangar@dnt.mui.ac.ir

Person responsible for scientific 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

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5514

Email

tavangar@dnt.mui.ac.ir

Dentistry

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 5514

Email

tavangar@dnt.mui.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

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

Person responsible for updating data**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