

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of Scrophularia striata Extract on pain relief aphthous stomatitis

#### Protocol summary

##### Study aim

Effects of Scrophularia striata Extract on Recurrent aphthous stomatitis recovery

##### Design

four arm parallel group randomised trial with blinded outcome. The number of participants in the study will be 100 patients.

##### Settings and conduct

This clinical trial will be conducted at the Dental School of Ilam University of Medical Sciences. Patients will be randomly assigned to intervention and control groups with tow- way blindness.

##### Participants/Inclusion and exclusion criteria

People with recurrent aphthous stomatitis less than 3 days old and over 7 years of age. People with underlying illnesses, recipients of drugs affecting aphthous stomatitis healing in the past three months and pregnant mothers will not be included.

##### Intervention groups

The interventional groups were 10%, 15% solution, control diphenhydramine syrup or serum physiology

##### Main outcome variables

Reduce inflammation and pain, healing and recurrent aphthous stomatitis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180327039152N1**

Registration date: **2018-04-28, 1397/02/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-28, 1397/02/08**

Update count: **0**

##### Registration date

2018-04-28, 1397/02/08

##### Registrant information

##### Name

Masoumeh Shohani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 84 3222 1286

##### Email address

shohani-m@medilam.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-06, 1397/01/17

##### Expected recruitment end date

2019-03-10, 1397/12/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Scrophularia striata Extract on pain relief aphthous stomatitis

##### Public title

Effects of Scrophularia striata Extract on Recurrent aphthous stomatitis recovery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Definitive diagnosis of minor oral aphthous by specialist dentistry Life span is 3 days or less. Age over 7 years.

###### Exclusion criteria:

Children under 7 years of age and those who are nervous and anatomical can not gargle Pregnancy Atypical cases of pests and cases suspected of Behcet's syndrome, Inflammatory bowel disease, or history of any type of

underlying illness that can predispose a person to aphthous . Drug and tobacco use Taking effective medications for wound healing, such as corticosteroids, anticoagulants, immunosuppressive drugs, chemotherapy Concomitant use of any topical drug for the treatment of aphthous The use of any type of topical or systemic analgesic, Use of any systemic pest treatment over the past 3 months

**Age**

From **7 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

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

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

We use the random block randomization method. In this way, we will produce eight paper sheets. we write on the two sheet of the letter I1 means Intervention 1 (Solution 10%), On the two sheet of the letter I2 means Intervention 2 (Solution 15%), On the two sheet of the letter C1 means Control1 (Diphenhydramine syrup), On the two sheet of the letter C2 means Control2 (Salin serum).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Mix the sheets together and place them in the drawer. By referring to each eligible patient, one of the sheets is drawn randomly. Based on this drawn sheet (I1, I2 or C1, C2), they will be assigned to one of the two intervention or control groups. It should be noted that the drawn sheets will not be returned to the drawer until all eight papers have been drawn out. After having drawn out randomly every eight sheets, all sheets are returned to drawer again and the above action again for the next eight to reach the desired sample size will continue.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ilam University of Medical Sciences

**Street address**

Pazhohesh blv.

**City**

Ilam

**Province**

Ilam

**Postal code**

6939177143

**Approval date**

2018-04-07, 1397/01/18

**Ethics committee reference number**

ir.medilam.rec.1396.128

**Health conditions studied****1****Description of health condition studied**

Recurrent aphthous stomatitis

**ICD-10 code**

K12.0

**ICD-10 code description**

Recurrent oral aphthae

**Primary outcomes****1****Description**

Pain relief for recurrent oral aphthous

**Timepoint**

At the first meeting with the participants and days 1, 2, 3, 5 and 7 after starting treatment

**Method of measurement**

use of visual analog scale (VAS)

**2****Description**

Wound healing rate

**Timepoint**

Admission and days 3 and 7

**Method of measurement**

Measuring the wound using a periodontal probe, in millimeters

**Secondary outcomes****1****Description**

The rate of recurrence of ulcers

**Timepoint**

Up to three months monthly

**Method of measurement**

Questions about the recurrence of ulcers by phone

## Intervention groups

### 1

#### Description

Intervention group: First: 10% solution

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group:second: 15% solution

#### Category

Treatment - Drugs

### 3

#### Description

Control group: First: Diphenhydramine syrup

#### Category

Placebo

### 4

#### Description

Control group: second: Salin serum

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dentistry Clinic, Ilam University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Reza Soltani

##### Street address

Ayatollah Heidari Ave

##### City

Ilam

##### Province

Ilam

##### Postal code

6939177143

##### Phone

+98 84 1335 1783

##### Email

mr-soltani77@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ilam University of Medical Sciences

##### Full name of responsible person

Dr. Gholam Reza Kalvandi

##### Street address

Pazhohesh Ave

##### City

Ilam

##### Province

Ilam

##### Postal code

6939177143

##### Phone

+98 84 3223 5724

##### Fax

+98 84 3223 5721

##### Email

kalvandi-gh@medilam.ac.ir

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Ilam 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

Ilam University of Medical Sciences

##### Full name of responsible person

Masoumeh Shohani

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

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##### Email

shohani-m@medilam.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ilam University of Medical Sciences

**Full name of responsible person**

Masoumeh Shohani

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Adherence to the principles of ethics in research

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

According to the ethics of research, sharing of individual data will not be done.

**When the data will become available and for how long**

Start the access period 6 months after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Use of data under the supervision and agreement of the Deputy of Research and Technology of the University and the project implementer

**From where data/document is obtainable**

Contact the University of Technology Research and Technology researcher project implementer and guidance shohani-m@medilam.ac.ir

**What processes are involved for a request to access data/document**

Contact to researcher project implementer and guidance Information acquisition Contact the University of Technology Research and Technology Written request Obtain permission

**Comments**

It is suggested that you coordinate with the researcher implementer if you have any questions. shohani-m@medilam.ac.ir

## Person responsible for updating data

### Contact

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Ilam University of Medical Sciences

**Full name of responsible person**

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