

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

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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

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+98 84 1335 1783

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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

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Masoumeh Shohani

Position

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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

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Masoumeh Shohani

Position

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Latest degree

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