

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evalotion and Comparison of Therapeutic effect for Persian medicine product (Sagi) and persica on wound size and pain severity of recurrent aphthous stomatitis

Protocol summary

Study aim

determination of therapeutic effect for Persian medicine product (Sagi) and persica on wound size and pain severity of recurrent aphthous stomatitis in patients referring to dental clinic of Shahid Sadoughi dental school in Yazd

Design

This study was an interventional (clinical trial), controlled group, with parallel randomized groups. After entering the study, the patients in the intervention group are treated with the traditional medicine (SAGI) and the persica. Use 15 ml of Saji mouthwash every 6 hours . In the control group, this process is also done with placebo and Presica

Settings and conduct

At first, among patients referring to Oral and Disease Department of Yazd Dental School, after complete clinical examinations and accurate medical history of patients and confirmation of pest diagnosis in them, randomly and through random numbers, intervention samples They are also selected in both groups.

Participants/Inclusion and exclusion criteria

Inclousion Criteria: Over 2 days after the onset of their aphthous ulcers. Exclousion criteria: They did not use any other therapies for their aphthous lesions before referring.

Intervention groups

In a group, use 15 ml of Saji mouthwash every 6 hours and keep 30 seconds in the mouth for each use. In this group, besides sagi, the persica is also prescribed Twice a day.. In the second group, use 15 ml of placebo mouthwash every 6 hours, and hold 30 seconds in the mouth for each use. In addition to the placebo, the persica is also prescribed Twice a day.

Main outcome variables

size of lesion; Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190408043200N1**

Registration date: **2019-05-01, 1398/02/11**

Registration timing: **prospective**

Last update: **2019-05-01, 1398/02/11**

Update count: **0**

Registration date

2019-05-01, 1398/02/11

Registrant information

Name

Mahdi Adl

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3534 7424

Email address

m.adl@mail.ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-10, 1398/02/20

Expected recruitment end date

2019-08-11, 1398/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evalotion and Comparison of Therapeutic effect for Persian medicine product (Sagi) and persica on wound size and pain severity of recurrent aphthous stomatitis

Public title

Evalotion and Comparison of Therapeutic effect for Persian medicine product (Sagi) and persica on wound size and pain severity of recurrent aphthous stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Over 2 days have passed since the onset of their aphthous ulcers

Exclusion criteria:

They did not use any other therapies for their aphthous lesions before referring

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 52

Randomization (investigator's opinion)

Randomized

Randomization description

A simple random method using a random number table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Central Office of Shahid Sadoughi University of Medical Sciences, Shahid Sadoughi Blvd,

City

Yazd

Province

Yazd

Postal code

8951737915

Approval date

2018-01-16, 1396/10/26

Ethics committee reference number

IR.SSU.REC.1396.182

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

size of lesion

Timepoint

The first and the fourth day after the visit

Method of measurement

By paper millimeter

2

Description

Intensity of pain

Timepoint

The first and the fourth day after the visit

Method of measurement

Through the standard scale(Visual Analog Scale(vas

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use 15 g of Sagi mouthwash every 6 hours and keep 30 seconds each time in the mouth. In this group, besides sagi, the persica is also prescribed Twice a day.

Category

Treatment - Drugs

2

Description

Control group: Use 15 g of placebo mouthwash every 6 hours and keep 30 seconds each time in the mouth. In this group, besides sagi, the persica is also prescribed Twice a day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

dental clinic of Shahid Sadoughi dental school in Yazd

Full name of responsible person

Mehdi Adl

Street address

Taleghani Blvd.

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cllinik@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzayi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Mehdi Adl

Position

Phd candidate

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Majid Emtiazy

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Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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Position

Phd candidate

Latest degree

Medical doctor

Other areas of specialty/work

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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