Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ofplacebo 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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Province
Yazd
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8951737915
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+98 35 3733 0122
Email
clinik@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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Taleghani Blvd.
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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
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Associate professor
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Person responsible for updating data

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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Province

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Email

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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