Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Therapeutic Efficacy of Pistacia atlantica essential oil in the treatment of Recurrent Aphthous Stomatitis referred to Kowsar hospitals of Sanandaj in 2022

Protocol summary

Study aim
The anti-pest effect of plant coriander essential oil Becomes.

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 per 100 patients, a random number table is used for randomization.

Settings and conduct
Sampling is done in parallel in two groups until the number of samples is completed. Patients as well as clinical caregivers are blind (double-blind) to belonging to any of the control intervention groups. The intervention group will be prescribed ointment or essential oil of coriander gum and the control group will be given triadent ointment in the same form. How to use it is that, topically 3 times a day, each time 10 drops are poured on a small piece of penny for 20 to 30 seconds on the aphthous lesion. Follow-up time to observe changes and improvement in aphthous lesions will be on days zero (during the first visit to the doctor), 1 (first examination) on days 7 and 10 (follow-up) after starting treatment, which will be done by referring patients to the clinic of Kowsar hospital of Sanandaj.

Participants/Inclusion and exclusion criteria
Inclusion Log: Wound onset less than 2 days, age group 18 years and older Exclusion: Allergy to the compounds and drugs used, failure to follow treatment instructions, underlying diseases and pregnancy, use of other antibiotics

Intervention groups
In the intervention group, Bene tree gum essential oil will be prescribed to the studied patients, and to the control group, Trident ointment will be prescribed in the same form and in the same form with the same taste and smell.

Main outcome variables
Number of wounds, wound size, pain and burning, erythema, exudate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211206053290N1**
Registration date: **2023-04-22, 1402/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-22, 1402/02/02**
Update count: **0**

Registration date
2023-04-22, 1402/02/02

Registrant information

Name
Jamal Amjadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 87 3322 6566

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-05-21, 1402/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Therapeutic Efficacy of Pistacia atlantica essential oil in the treatment of Recurrent Aphthous Stomatitis referred to Kowsar hospitals of Sanandaj in 2022

Public title
Therapeutic Efficacy of Pistacia atlantica essential oil in the treatment of Recurrent Aphthous Stomatitis referred to Kowsar hospitals of Sanandaj

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
No more than 2 days have passed since the onset of aphthous ulcers. Have not used any other treatment for their wounds before going to the clinic. Patients have completed the consent to participate in the trial. Be in the age group over 18 years. People with a clear history of plague should be reported at least twice a year.

Exclusion criteria:
People are allergic to the compounds and drugs used in the trial. Failure to follow the recommended instructions during the study Patients with systemic diseases such as diabetes, asthma, renal and hepatic insufficiency, epilepsy, blood and glandular disorders as well as pregnant women Patients taking antibiotics or anti-inflammatory drugs for other reasons.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The sample will be assigned to 2 groups at random, so that patients with the condition will be assigned to a double block (A and B) by the researcher. Then a package containing 100 cards with one of the letters A and B (50 each) is considered to randomly select a card from the package and enter one of the groups according to the Latin letter. In this way, 50 people are assigned to each group. Sampling is done in parallel in 2 groups until the number of samples is completed.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding (double-blind) means that both the participants and the researchers or the outcome assessors will not be aware of the random assignment of the study subjects to one of the intervention or control groups, because the random assignment based on blocking to one of the groups It was done with special numbers and using sealed envelopes, and receiving the medicine and placebo, considering that they are the same in color, shape, taste and smell, they are not able to know about the allocation of study groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kurdistan University of Medical Sciences

Street address
Pasdaran Ave, In front of Shadi Hotel

City
Sanandaj

Province
Kurdistan

Postal code
۱۳۴۴۶۶۶۱۷۷

Approval date
2023-01-18, 1401/10/28

Ethics committee reference number
IR.MUK.REC.1401.359

Health conditions studied

1

Description of health condition studied
Aphthous Stomatitis

ICD-10 code
ICD-10 K12

ICD-10 code description
Aphthous stomatitis

Primary outcomes

1

Description
Follow-up time to observe changes and improvement in aphthous lesions will be on days zero (during the first visit to the doctor), 1 (first examination) on days 7 and 10 (follow-up) after starting treatment, which will be done by referring patients to the clinic. The studied variables include the number of wounds, the size of the wounds, the amount of pain and burning, and the amount of erythema and exudate. This information will be recorded each time the patient is examined in a special form along with the patient's demographic

information.

Timepoint

Follow-up time to observe changes and improvement in aphthous lesions will be on days zero (during the first visit to the doctor), 1 (first examination) on days 7 and 10 (follow-up) after starting treatment, which will be done by referring patients to the clinic.

Method of measurement

Wound size will be measured by a special Williams dental probe. Also, the number of mouth ulcers will be counted at the beginning of the day and during the study period. The scale of burning and pain consists of a line of 10 cm, which means zero, no pain and 10 maximum pain. The patient determines the points that indicate pain, then from zero to that point will be measured and a numerical scale from one to 100 mm will be recorded.Pain intensity in patients will be measured based on the Visual Analog Scale (VAS). This pain scale represents a 10 cm line printed with markers at each end on a piece of paper. It is "painless" at one end and "worst pain" or "indescribable pain" at the other. The person places a cross × on the line to indicate the severity of their pain. A doctor then measures the line with a ruler to get a pain score.For children, pain scales using face images are commonly used. A child may express pain with pictures of eight different faces with different expressions. The child chooses a face that feels more in tune with their current level of pain.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will be prescribed Teriadent ointment. How use it is that, The gel will be applied topically 3 times a day (with an approximate weight of 200 mg containing 3 mg of essential oil) on the lesion on the swab for 20 to 30 seconds.(Product of Zhiran Daneshpojohan company)

Category

Treatment - Drugs

2

Description

Control group: The control group will be prescribed Teriadent ointment. How use it is that, The gel will be applied topically 3 times a day (with an approximate weight of 200 mg containing 3 mg of essential oil) on the lesion on the swab for 20 to 30 seconds.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital of Sanandaj

Full name of responsible person

Dr. Jamal Amjadi

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Pasdaran Ave, Front of Shadi Hotel

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Kurdistan

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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

Sanandaj 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
Sanandaj University of Medical Sciences

Full name of responsible person
Dr. Jamal Amjadi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
All patient information will be kept confidential by researchers. Data analysis and article publishing will also be done.

When the data will become available and for how long
From 2023 and 1 year before the publication of the results

To whom data/document is available
Researcher.

Under which criteria data/document could be used
The data file will be available as an article publication

From where data/document is obtainable
The main performer

What processes are involved for a request to access data/document
Formal request to the Vice Chancellor for Research and Technology of the University and the main executor

Comments