

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Achillea Millefolium with Triamcinolone Acetonide Mucoadhesive Film Effects in Treating the Symptoms and Reducing Period of Recurrent Minor Aphthous Stomatitis

Protocol summary

Study aim

application of yarrow mucoadhesive film and triamcinolone mucoadhesive film to improve symptoms and reduce the duration of minor aphthous lesions and comparing two films

Design

Randomized, double-blind, randomized clinical trial on 60 patients using random allocation service software.

Settings and conduct

Department of oral and dental disease medical university of isfahan dentistry faculty double blinded

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients in the age group of 16 to 50 years with a minor aphthous lesion who has been diagnosed by an oral pathologist. Less than 48 hours after the onset of the pest Exclusion criteria: pregnancy and lactation, concomitant treatment with another drug, allergy to herbs or triamcinolone, immunodeficiency, as well as current or past head and neck radiotherapy and current chemotherapy, neuropsychiatric disorders and lack of cooperation, consumers Systemic steroid drugs, immune regulators and nonsteroidal anti-inflammatory drugs, patients with a history of ulcerative colitis, Behcet's disease, severe anemia and Crohn's disease.

Intervention groups

Intervention group 1: Yarrow mucoadhesive film is applied on aphthous lesion every day after each meal and before bedtime (4 times daily). Intervention group 2: Triamcinolone acetonide mucoadhesive film is applied to aphthous lesion daily after each meal and before bedtime (4 times daily).

Main outcome variables

the pain The size of the aphthous lesion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200303046685N3**
Registration date: **2022-04-11, 1401/01/22**
Registration timing: **retrospective**

Last update: **2022-04-11, 1401/01/22**

Update count: **0**

Registration date

2022-04-11, 1401/01/22

Registrant information

Name

Fahimeh Pakravan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3436 8793

Email address

pakravan@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Achillea Millefolium with Triamcinolone

Acetonide Mucoadhesive Film Effects in Treating the Symptoms and Reducing Period of Recurrent Minor Aphthous Stomatitis

Public title

Comparison of Adhesive Pharmacological Form of Achillea Millefolium with Triamcinolone Acetonide Effects in Treating the Symptoms and Reducing Period of Recurrent Aphthous Stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients in the age group of 16 to 50 years with a minor oral stomatitis that has been diagnosed by an oral disease specialist. No more than 24 hours after the onset of the minor oral stomatitis.

Exclusion criteria:

Pregnancy and lactation concomitant treatment with other drugs allergy to herbs or triamcinolone immunodeficiency current and past head and neck radiotherapy and current chemotherapy neuropsychiatric disorders and lack of cooperation systemic steroid, Immune regulators and non-steroidal anti-inflammatory drugs users Patients with a history of ulcerative colitis Behcet's disease, severe anemia and Crohn's disease

Age

From **16 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Among patients suffering from minor aphthous stomatitis who referred to dentistry department of Isfahan Medical University, 60 patients who have been examined by supervisor and have met the eligibility criteria, will enter the study and a number will be assigned to every patient. Then they will be divided into two intervention groups using block randomization (block size=30) through the random allocation service software. For allocation concealment, sealed coded boxes with randomized sequence with the same size and weight will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the participant and the investigator are not aware of the administered medication because of the similarity of the films in appearance, color and smell provided to the participants.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjerib Ave, Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-08-23, 1400/06/01

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.275

Health conditions studied

1

Description of health condition studied

Recurrent minor Aphthous stomatitis

ICD-10 code

K12.0

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

pain

Timepoint

Days two, four and six of the study

Method of measurement

VAS (visual analogue scale)

2

Description

The size of the aphthous lesion

Timepoint

Days two, four and six of the study

Method of measurement

ruler (millimeter)

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Achillea millefolium adhesive film, every day after every meal and before bed, the duration of treatment for a week or until the lesions heal, whichever occurs sooner

Category

Treatment - Drugs

2

Description

second intervention group: : Triamcinolone acetamide adhesive film with 1mg active ingredient, made by Dr Saniee Pharmaceutical Company, every day after every meal and before bed, the duration of treatment for a week or until the lesions heal, whichever occurs sooner

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Oral Diseases, Isfahan School of Dentistry

Full name of responsible person

Fahimeh Pakravan

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Department of oral medicine Faculty of Dentistry; Isfahan University of Medical Sciences; Hezarjarib street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansoor Siavash

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Fahimeh Pakravan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only information such as main consequence or the like can be shared.

When the data will become available and for how long

Access to the results immediately after publication

To whom data/document is available

Open access

Under which criteria data/document could be used

Access to data is possible only after formal permission from corresponding author

From where data/document is obtainable

Corresponding author

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

Formal letter or email

Comments