Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 31 3436 8793

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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 stomititis 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 refereed to dentistry department of isfahan medical univeristy, 60patients 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
Isfehan

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 acetonide 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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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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Department of Oral Medicine Faculty of Dentistry; Isfahan University of Medical Sciences; Hezarjarib street
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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
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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