Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparison between the Effectiveness of two different Oral pastes, containing Triamcinolone and Licorice, on Minor Aphthous lesions: A triple blind randomized clinical trial

Protocol summary

Study aim
Determining the Effectiveness of two types of oral pastes containing Licorice extract and Triamcinolone on oral Aphthous ulcers Using Herbal medicines (Licorice extraction) with fewer side effects to heal Aphthous lesions. Study the Effect of medicine on the size, pain and duration of lesion healing.

Design
A clinical trial has three groups receiving standard treatment, intervention and placebo or control group, triple blind, randomized, third phase on 60 patients, Using Balance block randomization

Settings and conduct
Patients who during the first 24 hours of the lesion appearing referred to Qazvin Dental School were examined by two oral medicine specialists and after confirming Aphthous lesions, Being informed and receiving consent, they entered one of the three groups completely randomly. The medicine containers will be the same and Coded and Given to the patient randomly by the secretary of the department, The examiner and the patient will be unaware of the contents of the medicine.

Participants/Inclusion and exclusion criteria
Inclusion criteria: No systemic disease (Hypertension, Diabetes, Hyperlipidemic, Bechet's disease, Rheumatoid disease) Not using medicines, cigarettes, alcohol and addiction. No-entry criteria: Allergic to herbal medicines. Oral ulcers that are not aphthous lesions. More than 48hrs passed from the incidence of the lesion. Use of medicines, cigarettes, alcohol and addiction. Systemic diseases

Intervention groups
Frist group (Standard treatment group): Using Oral paste containing Triamcinolone. The second group (Intervention group): Oral paste containing Licorice extract The third group (Control group): Placebo oral paste without active substance

Main outcome variables
Size, Pain and Healing duration of the Lesion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210519051341N1**
Registration date: **2021-09-23, 1400/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-23, 1400/07/01**
Update count: **0**

Registration date
2021-09-23, 1400/07/01

Registrant information

Name
masoume tork cheshme soltani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-30, 1400/06/08

Expected recruitment end date
2021-09-30, 1400/07/08

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparison between the Effectiveness of two different Oral pastes, containing Triamcinolone and Licorice, on Minor Aphthous lesions: A triple blind randomized clinical trial

Public title
A comparison between the Effectiveness of two different oral pastes, Containing Triamcinolone and Licorice, on minor Aphthous lesions: A triple blind randomized clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Minor Aphthous ulcers who have been visited within the first 24 hours of incidence of the lesion. Patients do not have any systemic diseases (Hypertension, Diabetes, Hyperlipidemia, Behcet disease, Rheumatism disease) Don't use medicine, cigarettes, alcohol and addiction
Exclusion criteria:
An oral ulcer that is not an Aphthous lesion More than 48hrs passed from incidence of the lesion Allergic to herbal medicines Use of medicine, cigarettes, alcohol and addiction Systemic diseases
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are divided into three treatment groups A, B, C using the Balance block randomization method, the size of each block is 6 and the total number of blocks is 10. Balanced randomization allocation method for participants, in a randomized clinical trial study of the effect of Oral paste, containing Triamcinolone (group A), placebo (group B) and Licorice(group C) in reducing the size, pain and healing duration of the lesion. Randomization unit: individual Randomization tool: based on statistical software
Blinding (investigator's opinion)
Triple blinded
Blinding description
These patients are divided into three groups of triamcinolone, Licorice and placebo (10 blocks of 6) based on random allocation. Patients in the first group are given triamcinolone gel under the brand name Triadent 10 grams (from Raha Daroo Company) three times a day, the second group is given an oral gel containing Licorice and the third group is given a placebo gel. The containers in which the drugs are placed are very similar to each other and the contents are unknown. This study is triple blind and the patient, researcher and statistician are unaware of the type of drug which is given
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Qazvin University of Medical Sciences, Bahonar Blv, Qazvin
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Province
Qazvin
Postal code
3419915315
Approval date
2021-08-30, 1400/06/08
Ethics committee reference number
IR.QUMS.REC.1400.246

Health conditions studied

1

Description of health condition studied
Recurrent oral Aphthae
ICD-10 code
K12.0
ICD-10 code description
Recurrent oral Aphthae

Primary outcomes

1

Description
Amount of pain

Timepoint
Before taking oral paste and the third, fifth and seventh days of treatment
Method of measurement
On the visit days, we ask the patient to mark the amount of pain on the Visual Analogue Scale

2

Description
Healing duration
Timepoint
Before taking oral paste and the third, fifth and seventh days of treatment
Method of measurement
Days spent until complete healing of the lesion

3

Description
Size of the lesion
Timepoint
Before taking oral paste and the third, fifth and seventh days of treatment
Method of measurement
The largest diameter of the lesion is measured with the dental probe in millimetres

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the intervention group receive a drug containing the Licorice active ingredient. They are trained to apply the gel on the Aphthous lesion 3 times a day after brushing and to avoid eating and drinking for half an hour after that. The drug consists of the Licorice active ingredient with 5% concentration and Carboxymethyl Cellulose (CMC).
Category
Treatment - Drugs

2

Description
Standard treatment group: Triamcinolone (Trident 0.1%) is used as standard treatment. They should apply the oral paste on the Aphthous lesion 3 times a day after brushing and avoid eating and drinking for half an hour after that.
Category
Treatment - Drugs

3

Description
Control group: This group receives a placebo (containing no active substance). The placebo only consists of Carboxymethyl Cellulose (CMC). They should apply the placebo gel on the Aphthous lesion 3 times a day after brushing and avoid eating and drinking for half an hour after that.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Oral and maxillofacial medicine, school of dentistry, Qazvin University of Medical Sci
Full name of responsible person
Mahdie Zarabadipour
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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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Dept of research Qazvin University of Medical Sciences, Shahid Beheshti Ave, Qazvin, IRAN
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Web page address
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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
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Mahdie Zarabadipour
Position
Associate professor, oral and maxillofacial medicine specialist
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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