Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the effectiveness of Glycyrrhiza glabra solution with Diphenhydramine Elixir in the management of pain and duration of Recurrent Aphthous Stomatitis

Protocol summary

Study aim
Comparison of the efficacy of Glycyrrhiza glabra in Diphenhydramine solution with Diphenhydramine Elixir in the management of Recurrent aphthous Stomatitis

Design
Clinical trials with parallel , double -blind, randomized groups

Settings and conduct
This study is conducted in Birjand, and in this study,major researcher, participants and data collectors are kept blind.

Participants/Inclusion and exclusion criteria
Criteria for entering the study: Patients with RAS with duration of 1 day of begining of their symtoms Exit criteria: 1. Use of systemic Aphthous treatment (over the past three months) and topical treatment during the procedure 2. Atypical Aphthous cases and cases suspected of Behcet's syndrome, inflammatory bowel disease, and ... 3. Pregnant or lactating women 4. Patient with Diabetes 5. High blood pressure 6. Duration of the Aphthous more than one day 7. The patients who did not sign the letter of informed consent

Intervention groups
Patients with RAS in Birjand

Main outcome variables
1. If the licorice extract was effective, it will be used as a treatment for recurrent oral wounds 2. If the licorice extract was effective, it will be used in other recurrent oral ulcers, including in patients with Behcet's syndrome, or oral ulcers with inflammatory bowel diseases (Crohn's disease and ulcerative colitis). 3. If the licorice extract was effective, It will be used in the treatment of mucositis due to radiation therapy or chemotherapy for cancers, which due to severe symptoms, occasionally lead to changes or even discontinuation of treatment regimens.

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT20180407039213N1**
Registration date: **2018-06-29, 1397/04/08**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-29, 1397/04/08**
Update count: **0**

Registration date
2018-06-29, 1397/04/08

Registrant information

Name
Neda Asadi mehr

Name of organization / entity

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Iran (Islamic Republic of)

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+98 51 4724 5342

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-20, 1397/03/30

Expected recruitment end date
2018-08-21, 1397/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of Glycyrrhiza glabra solution with Diphenhydramine Elixir in the management of pain and duration of Recurrent Aphthous Stomatitis

Public title
The effectiveness of licorice solution in Recurrent Aphthous Stomatitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with RAS symptoms for less than 1 day

Exclusion criteria:
The patients who did not sign the letter of informed consent Patient with hypertension (greater than 80/130) Use of systemic aphthous treatment (over the past three months) and topical treatment during the procedure Atypical aphthous cases and cases suspected of Behcet's syndrome, inflammatory bowel disease. Pregnant or lactating women Patients with Diabetes Patients with RAS symptoms for more than 1 day

Age
From **15 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Individual simple randomization by sealed envelope

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, participants, major researcher, data collectors were kept blind

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Birjand University of Medical Sciences

Street address
Dentistry faculty, Birjand University of Medical Sciences, Ghaffari street, Birjand, Iran

City
Birjand

Province
South Khorasan

Postal code
۹۷۱۷۸۵۳۵۷۷

Approval date
2018-03-06, 1396/12/15

Ethics committee reference number
Ir.bums.REC.1396.338

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
Improvement of pain and duration of Recurrent Aphthous Stomatitis symptoms

Timepoint
Measurement of pain intensity and healing of wound in second, third, and fifth days of intervention

Method of measurement
Visual Analogue Scale (VAS) to measure pain and physical examination to detect wound healing

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with RAS gargle licorice 5% in Diphenhydramine every 6 hours (3 ml for 3 minutes) until improvement

Category
Treatment - Drugs

2

Description
Control group: RAS patients gargle Diphenhydramine without licorice every 6 hours (3 ml for 3 minutes) until

improvement

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Birjand University of Medical Sciences

Full name of responsible person

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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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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Akbari Narjes

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Because its not mandatory yet
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
Publication of a paper in academic journals
When the data will become available and for how long
From 2019
To whom data/document is available
Anyone who wishes to access the data.
Under which criteria data/document could be used
To achieve the aims in the approved proposal.
From where data/document is obtainable
Proposal may be submitted up to 24 months following article publication.
What processes are involved for a request to access data/document
Proposal will be available up to 24 months following article publication.
Comments