Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison effect of a herbal drug (Golnar) and triamcinolon acetonide on healing ulcer in Recurrent aphthous stomatitis patients (clinical trial study)

Protocol summary

Summary

In this double-blind clinical Trial study, 60 patients with minor aphthous ulcer which no medicine used and no systemic disease were enrolled in study. The aim of this study was evaluation of therapeutic effect of Golnar gel on minor aphthous ulcer and comparison with Triadent. Patients were divided randomly into three groups of Golnar, Triadent and Placebo as the form of each three type of medicine was similar completely and was coded A,B ,C by the third person. every time one of coded medicine was given to the patients randomly. nor clinician nor patients didn’t understand type of medicine. The gel applied three times a day by patients. The pain intensity was evaluated by VAS. More ever in recall examination that was done by clinician , size of ulcer and healing time of ulcer was recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606063251N6**
Registration date: **2017-01-25, 1395/11/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-25, 1395/11/06

Registrant information

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Atefeh Tavangar
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

governmental

Expected recruitment start date

2015-06-10, 1394/03/20

Expected recruitment end date

2016-08-03, 1395/05/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison effect of a herbal drug (Golnar) and triamcinolon acetonide on healing ulcer in Recurrent aphthous stomatitis patients (clinical trial study)

Public title

efficacy of golnar on aphthous ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 24 to 48 initial hours of wound; history of recurrent ulcer; no drug has used; no systemic disease
exclusive criteria: major and herpetiform aphthous; systemic disease; antibiotic drug using and any type of cortocosteroid medicine

Age

No age limit

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
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 Siences
Street address
Isfahan University of Medical Siences, Darvazeh Shiraz
City
Isfahan
Postal code
Approval date
2016-03-07, 1394/12/17
Ethics committee reference number
IR.MUI.EC.1394.3.1027

Health conditions studied

1

Description of health condition studied
Aphthous stomatitis
ICD-10 code
K12.0
ICD-10 code description
Recurrent oral aphthae

Primary outcomes

1

Description
Size of wound
Timepoint
first, third, and fifth day after intervention
Method of measurement
ruler

2

Description
pain
Timepoint
Before study ,first, third, and fifth day after onset of study
Method of measurement
VAS scale

3

Description
Healing ulcer
Timepoint
before onset of study and after end of the study
Method of measurement
examination

Secondary outcomes

empty

Intervention groups

1

Description
Triadent orabase , thrice a day ,until complete remission of aphthous ulcer, Raha Pharmaceutical Co
Category
Treatment - Drugs

2

Description
Placebo , thrice a day , until complete remission of ulcers, School of Phamacy, Isfahan university of Medical Science
Category
Placebo

3

Description
Golnar orabase. thrice a day , until complete remission of ulcers, School of Phamacy, Isfahan university of Medical Science
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dentistry school of Isfahan university of medical science
Full name of responsible person
Atefeh tavangar
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Hezar jerib S, Isfahan university of medical science

City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chanceller for research, Isfahan University of Medical Siences
Full name of responsible person
Omid Savabi
Street address
Hezar jerib S, Isfahan University of Medical Siences
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chanceller for research, Isfahan University of Medical Siences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty

Data Dictionary *empty*