Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of five doses of mucoadhesive prednisolone (0.5, 1, 2.5, 5, 10mg) in treatment of recurrent aphthous stomatitis: A Triple blind randomized clinical trial

Protocol summary

Summary

To compare five doses of mucoadhesive prednisolone (0.5, 1, 2.5, 5, 10mg) in treatment of recurrent aphthous stomatitis (RAS). 225 patients aged 18-15 yrs with at least 3 months presentation of RAS and at least one breakout per month that have no other diseases such as behcet syndrome, DM, hepatic diseases etc. will be recruited to be treated with one of the five different doses of mucoadhesive prednisolone. The patients will put the mucoadhesive patches on their aphthous ulcers every 12 hours each time for 30 minutes (according to the protocol). The groups will be measured for size and number of ulcers, severity of pain and burning sensation, before the treatment and then every day for 7 days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110037710N1**
Registration date: **2012-07-22, 1391/05/01**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-07-22, 1391/05/01

Registrant information

Name

Farzad Gheshlaghi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1669 7823

Email address

gheshlaghi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of five doses of mucoadhesive prednisolone (0.5, 1, 2.5, 5, 10mg) in treatment of recurrent aphthous stomatitis: A Triple blind randomized clinical trial

Public title

Comparison of five doses of mucoadhesive prednisolone in treatment of recurrent aphthous stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: People aged 18-45 years; at least 3 months presentation of RAS; at least 1 breakout of disease each month; not responding to any medication. Exclusion criteria: systemic disease such as: diabetes, liver disease, Gastro-intestinal disease, kidney disease, Rheumatologic disease or behcet syndrome; people with teched CBC lab data; patients who take immunosupressive / immunomodulant medicine.

Age

From **18 years** old to **45 years** old

Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **225**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Medical Ethics Committee, Isfahan University of Medical Sciences
Street address
No 3, 4th department of Gostaresh departments, Isfahan university of medical sciences, Hazarjarib st.
City
ISfahan
Postal code
Approval date
2011-03-21, 1390/01/01
Ethics committee reference number
190164

Health conditions studied

1

Description of health condition studied
Recurrent Aphthous Stomatitis
ICD-10 code
K12
ICD-10 code description
Stomatitis and related lesions

Primary outcomes

1

Description
number of ulcers
Timepoint
before intervention and then every 24 hour for 6 days
Method of measurement
observation

2

Description
size of ulcers
Timepoint
before intervention and then every 24 hour for 7 days
Method of measurement
with caliper

3

Description
Severity of pain and burning sensation
Timepoint
before intervention and then every 24 hour for 7 days
Method of measurement
Visual Analogue Scale Score

Secondary outcomes

empty

Intervention groups

1

Description
3rd group : Intervention : the patients will put mucoadhesive prednisolone 2.0 mg on their ulcers every 12 hours and each time for 30 minutes. The treatment continues for 7 days.
Category
Treatment - Drugs

2

Description
1st group : Intervention : the patients will put mucoadhesive prednisolone 0.5 mg on their ulcers every 12 hours and each time for 30 minutes. The treatment continues for 7 days.
Category
Treatment - Drugs

3

Description
2nd group : Intervention : the patients will put mucoadhesive prednisolone 1.0 mg on their ulcers every 12 hours and each time for 30 minutes. The treatment continues for 7 days.
Category
Treatment - Drugs

4

Description
4th group : Intervention : the patients will put mucoadhesive prednisolone 5.0 mg on their ulcers every

12 hours and each time for 30 minutes. The treatment continues for 7 days.

Category

Treatment - Drugs

5

Description

5th group : Intervention : the patients will put mucoadhesive prednisolone 10.0 mg on their ulcers every 12 hours and each time for 30 minutes. The treatment continues for 7 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin clinic -super specialty Alzahra hospital

Full name of responsible person

Street address

City

ISfahan

2

Recruitment center

Name of recruitment center

Skin clinic, super specialty Nur-ali Asqar hospital

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of medical sciences

Full name of responsible person

Dr. Peiman Adibi

Street address

Hazarjarib st.

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Isfahan University of medical sciences

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

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Farzad Gheshlaghi

Position

Forensic Medicine

Other areas of specialty/work

Street address

No 4, Behesht-ain alley, south Mollasadra st.

City

Isfahan

Postal code

Phone

+98 31 1669 7823

Fax

Email

gheshlaghi@med.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. farzad Gheshlaghi

Position

Forensic Medicine

Other areas of specialty/work

Street address

No 4, Behesht-ain alley, south Mollasadra st.

City

Isfahan

Postal code

Phone

+98 31 1669 7823

Fax

Email

gheshlaghi@med.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of medical sciences

Full name of responsible person

Dr. Farzad Gheshlaghi

Position

Other areas of specialty/work
Street address
City
Isfahan
Postal code
Phone
Fax
Email
gheshlaghi@med.mui.ac.ir
Web page address

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