

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparative study of Muco-adhesive (Aphtogel) in treatment of oral minor Aphthous ulcer with placebo

Protocol summary

Summary

Aim of the study: Comparative study of muco-adhesive patch containing 0.01 mg Triamcinolone with placebo in symptomatic treatment of Minor Oral Aphthous ulcer. Inclusion and exclusion criteria: presence of Minor oral Aphthous ulcer- No history of any systemic disease and no previous application of any drug for treatment of aphthous. Population study: In this double blind clinical trial, a muco-adhesive with dual aims of dressing meanwhile concentration of drug on Aphthous ulcer, have been manufactured by adding Triamcinolone to muco-adhesive base and applied to 40 patients. From 23 of them who took part in all three appointments with three days interval, 14 received drug and 9 received placebo. Amount of pain evaluated by Visual analogue scale and maximum diameter of ulcer were measured by millimeter.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111057999N1**

Registration date: **2011-12-12, 1390/09/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-12, 1390/09/21

Registrant information

Name

Gholamreza jahanshahi

Name of organization / entity

Isfahan university of medical sciences-school of dentistry

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2879

Email address

jahanshahi@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences-School of Dentistry-Vice chancellor of research

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2011-01-21, 1389/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of Muco-adhesive (Aphtogel) in treatment of oral minor Aphthous ulcer with placebo

Public title

study of Aphtogel in treatment of oral aphthous

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of minor oral aphthous ulcer; Age of patients between 20 -60 years; completion of the consent form by the patient Exclusion criteria: patient age less than 20 years or more than 60 years; History of any systemic disease; previous consumption of another drug for treatment of aphthous

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 23

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

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Azadi Square, Isfahan, Iran

City

Isfahan

Postal code

8174673461

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

24604/4/12/پ

2

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Azadi Square, Isfahan, Iran

City

Isfahan

Postal code

81747-73461

Approval date

2009-06-07, 1388/03/17

Ethics committee reference number

24604/4/12/پ

Health conditions studied

1

Description of health condition studied

Minor Oral Aphthous Ulcer

ICD-10 code

K12.5

ICD-10 code description

Recurrent oral aphthae

Primary outcomes

1

Description

Amount of pain

Timepoint

Three days interval

Method of measurement

Visual analogue scale

2

Description

Size of Ulcer

Timepoint

Three days interval

Method of measurement

Milimeter Ruler

Secondary outcomes

1

Description

Decrease of pain

Timepoint

Three days interval

Method of measurement

visual analogue scale

2

Description

Decrease in size of ulcer

Timepoint

Three days interval

Method of measurement

Milimeter ruler

Intervention groups

1

Description

Applying of Aphtogel with 0.01 mg Triamcinolone on the ulcer 4 times a day for 1 week

Category

Treatment - Drugs

2

Description

Applying of Aphtogel without Triamcinolone on the ulcer
4 times a day for 1 week

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaede Dental Clinic

Full name of responsible person

Dr.Gholamreza jahanshahi

Street address

Ghaede Dental clinic, Alley Jahannamma,
Babolrahmeh Street, Emam Hosien Square, Isfahan,
Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Dentistry-Vice chancellor of Research

Full name of responsible person

Dr.Omid Savabie

Street address

School of Dentistry, Isfahn University of Medical
Sciences, Azadi Square, Isfahan, Iran

City

Isfahan

Grant name

288057

Grant code / Reference number

46970

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

Yes

Title of funding source

School of Dentistry-Vice chancellor of Research

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

School of Dentistry, Isfahan University of Medical
Sciences

Full name of responsible person

Dr.Gholamreza jahanshahi

Position

Associate professor/Ms of Oral and Maxillofacial
Pathology

Other areas of specialty/work

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**Person responsible for scientific
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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