Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Efficacy of Punica Granatum Extract in the Management of Recurrent Apthous Stomatitis

Protocol summary

Summary

Recurrent aphthous stomatitis (RAS) is a common , painful and ulcerative disorder of oral cavity with unknown etiology . No cure exists and topical application of medications aims to reduce pain associated with this condition. The aim of this study was to evaluate the efficacy of Punica granatum (PG) extract on the management of RAS. Fourty patients with RAS participated in this randomized, double-blind, placebo-controlled study. During three episodes of RAS the efficacy of topical PG gel 10% was evaluated. Patients were randomly assigned to use placebo gel or PG gel daily. The time of pain elimination and the duration of complete healing were recorded and the associated pain during this time span (day0, 1, 3, 5, 7) were recorded by patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112273251N2**
Registration date: **2012-02-07, 1390/11/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-02-07, 1390/11/18

Registrant information

Name

Atefeh Tavangar

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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tavangar@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vica-chancellery for research, Isfahan University of Medical Sciences

Expected recruitment start date

2007-03-25, 1386/01/05

Expected recruitment end date

2008-06-18, 1387/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of Punica Granatum Extract in the Management of Recurrent Apthous Stomatitis

Public title

The Efficacy of Golnar on Recurrent Apthous Stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-patients with minor aphthea; 2-active phase of ulcer (24-48 first hours). Exclusion critria: 1-patients with any systemic disease; 2-patients taking anti-inflammatory or analgesic drugs; 3- patients with major or herpetiform.

Age

From **18 years** old to **47 years** old

Gender

Both

Phase

3

Groups that have been masked
No information
Sample size
Target sample size: **34**
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, vica-chancellary for research
City
Isfahan
Postal code
Approval date
2007-07-01, 1386/04/10
Ethics committee reference number
386229

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
pain
Timepoint
days 0, 1, 3, 5
Method of measurement
VAS

Secondary outcomes

1

Description
the time of complet healing ulcer
Timepoint
during active phase of RAS
Method of measurement
day

2

Description
the time of painless ulcer
Timepoint
during active phase of RAS
Method of measurement
day

Intervention groups

1

Description
Golnar, oral gel 10%,three times a day
Category
Treatment - Drugs

2

Description
placebo, frrous oxid oral gel, three times a day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
oral medicine part of school of dentistry, Isfahan university of medical sciences
Full name of responsible person
Atefeh Tavangar
Street address
Isfahan university of medical sciences, Hezarjerib street
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vica-chancellery for research of dentistry school
Full name of responsible person
Dr Omid Savabi
Street address

Vica-chancellery for research, Dentistry school, Isfahan University of Medical Sciences

City
Isfahan

Grant name

Grant code / Reference number

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

Title of funding source
Vica-chancellery for research of dentistry school

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
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Position
assistant professor of oral medicine

Other areas of specialty/work

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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