

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 2026

### The Efficacy of Punica Granatum Extract in the Management of Recurrent Aphthous 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. Forty 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)

###### Phone

+98 31 1792 2814

###### Email address

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 Aphthous Stomatitis

###### Public title

The Efficacy of Golnar on Recurrent Aphthous 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-chancellery 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**

Atefeh Tavangar

**Position**

assistant professor of oral medicine

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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**Position**

Assistant Professor of Oral Medicine

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## Person responsible for updating data

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Atefeh Tavangar

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Assistant Professor of Oral Medicine

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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