

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Turmeric in the treatment of recurrent aphthous stomatitis: a double blind and placebo controlled trial

#### Protocol summary

##### Summary

Recurrent aphthous stomatitis, or RAS, is a common oral disorder of uncertain etiopathogenesis for which symptomatic therapy only is available. There are several proposed medication for treatment but their efficacy are not ideal. The aim of this study is to evaluate the clinical efficacy of turmeric in the treatment of recurrent aphthous stomatitis in a double blind, placebo controlled and randomized trial. Methods: Setting A two week, double blind, placebo controlled and randomized trial in the ward of oral medicine at Tehran University of Medical Sciences. Study population Patients between 20 and 45 years old will be included if they present with 1-5 aphthous ulcers of less than 24 h duration. The ulcers diameter will not be greater than 6 mm and they do not suffer from acute or chronic diseases of the oral mucosa. Patients will be excluded from the study if they have concurrent clinical conditions including serious liver, kidney, and heart dysfunctions or if they have ulcers as a manifestation of a systemic disease process such as ulcerative colitis, Crohn's disease, Behcet's syndrome, or serious anaemia. To minimize the effect of confounding variables in the psycho-physiological component of the study, the patients should not have a history of alcohol or drug abuse and should not take any narcotic analgesics. Patients will be excluded if they have a history of systemic immunosuppressive therapy. Patients will be assigned randomly (by computer-generated random number list), to receive turmeric or placebo (25 in each group) Measurements After enrolment, the size of ulcers will be measured by the investigator, and pain was evaluated by the subjects based on visual analogue scale (VAS) before drug application (day 0) and at days 2, 6, 10 and 14.

#### General information

##### Acronym

Turmeric trial

#### IRCT registration information

IRCT registration number: **IRCT201107311556N28**

Registration date: **2011-07-31, 1390/05/09**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-07-31, 1390/05/09

#### Registrant information

##### Name

Shahin Akhondzadeh

##### Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5541 2222

##### Email address

s.akhond@sina.tums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

By a grant from Erphan Teb

#### Expected recruitment start date

2011-07-31, 1390/05/09

#### Expected recruitment end date

2011-09-30, 1390/07/08

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Turmeric in the treatment of recurrent aphthous

stomatitis: a double blind and placebo controlled trial

**Public title**

Turmeric in the treatment of recurrent aphthous stomatitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

50 Patients between 20 and 45 years old will be included if they present with 1-5 aphthous ulcers of less than 24 h duration. The ulcers diameter will not be greater than 6 mm and they do not suffer from acute or chronic diseases of the oral mucosa Patients will be excluded from the study if they have concurrent clinical conditions including serious liver, kidney, and heart dysfunctions or if they have ulcers as a manifestation of a systemic disease process such as ulcerative colitis, Crohn's disease, Behcet's syndrome, or serious anaemia. To minimize the effect of confounding variables in the psycho- physiological component of the study, the patients should not have a history of alcohol or drug abuse and should not take any narcotic analgesics. Patients will be excluded if they have a history of systemic immunosuppressive therapy.

**Age**

From **20 years** old to **45 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**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**

Tehran University of Medical Sciences

**Street address**

Keshavarz Blvd

**City**

Tehran

**Postal code****Approval date**

2011-04-21, 1390/02/01

**Ethics committee reference number**

13676

**Health conditions studied****1****Description of health condition studied**

Recurrent aphthous stomatitis

**ICD-10 code**

K 12.0

**ICD-10 code description**

Recurrent oral aphthae

**Primary outcomes****1****Description**

Decrease of pain

**Timepoint**

Before treatment and days 2, 4, 6, 10 and 14 after treatment

**Method of measurement**

VAS rating scale

**Secondary outcomes****1****Description**

Size of ulcers

**Timepoint**

Before drug application (day 0) and at days 2, 6, 10 and 14

**Method of measurement**

Diameters

**Intervention groups****1****Description**

Intervention group: Turmeric Jel (topical) three time a day by a swap

**Category**

Treatment - Drugs

**2****Description**

Control group: Placebo gel, three time a day (topical) by a swap

**Category**

Placebo

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Oral Medicine Ward, Imam Khomeini Complex Hospital

**Full name of responsible person**

Dr. Soheila Mani far

**Street address**

Imam Khomeini Complex Hospital

**City**

Tehran

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Erphan Teb

**Full name of responsible person**

Dr. Hamid Shirazi

**Street address**

No. 4, Barmak Valley, Alvan Street, Arjantine Sq.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Erphan Teb

**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

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehtan University of Medical Sciences

**Full name of responsible person**

Shahin Akhondzadeh

**Position**

Prof. of Clinical Psychopharmacology

**Other areas of specialty/work****Street address**

Psychiatric Research Center, Roozbeh Hospital

**City**

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**Postal code****Phone**

+98 21 6641 8466

**Fax****Email**

S.akhond@sina.tums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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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*