

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

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+98 21 5541 2222

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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

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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