

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Evaluation the effect of oral zinc sulfate therapy on burning severity in burning mouth syndrome

Protocol summary

Summary

the present study was designed to evaluation of the effectiveness of oral zinc sulfate to improve symptoms of burning mouth syndrome. Sixty patients from Zahedan Dental School would be selected. inclusion criteria: is patient's with burning mouth syndrome and exclusive criteria is patient's with known systemic disease, patient's under 18 years, pregnancy, patient's with oral denture. In each patient, is receiving zinc sulfate and control group receive placebo after finishing treatment, after 3 month patients will be evaluated for severity of burning.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312093133N5**
Registration date: **2014-09-26, 1393/07/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-26, 1393/07/04

Registrant information

Name

Fateme Arbabi Kalati

Name of organization / entity

Dental school of Zahedan

Country

Iran (Islamic Republic of)

Phone

+98 54 1244 1814

Email address

farbabi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2014-07-01, 1393/04/10

Expected recruitment end date

2015-07-02, 1394/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of oral zinc sulfate therapy on burning severity in burning mouth syndrome

Public title

Evaluation the effect of oral zinc sulfate therapy on burning severity in burning mouth syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patients with burning mouth syndrome
exclusive criteria : patients with known systemic disease;
patients under 18 years; pregnancy; patients with oral denture

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences, Hesabi
Squer, Zahedan, Iran Zahedan Sistan and Baluchestan
Iran, Islamic Republic Of

City

Zahedan

Postal code**Approval date**

2014-05-11, 1393/02/21

Ethics committee reference number

6334

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

burning mouth syndrom

ICD-10 code

F59

ICD-10 code description

Unspecified behavioural syndromes associated with
physiological disturbances and physical factors

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

decreasing of burning Mouth

Timepoint

after 3 months

Method of measurement

Visual analog scale

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

well being of xerostomia

Timepoint

3 months

Method of measurement

lent soma

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

In control group placebo capsules would be given to
patients for 3 month

Category

Treatment - Drugs

2**Description**

In intervention group zinc sulfate capsules (220 mg)
would be given to patients for 3 month

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of dentistry

Full name of responsible person

fateme Arbabi-Kalati

Street address

Oral medicine departeman, Faculty of dentistry,
Azadegan aven, Zahedan, Iran Zahedan Sistan and
Baluchestan Iran, Islamic Republic Of

City

Zahedan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences,

Full name of responsible person

Hamidreza Sagheb

Street address

Zahedan University of Medical Sciences, Hesabi
Squer, Zahedan, Iran Islamic Republic Of

City

Zahedan

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

Yes

Title of funding source

Zahedan University of Medical Sciences,

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

Faculty of dentistry

Full name of responsible person

Fateme Arbabi-Kalati

Position

lecturer

Other areas of specialty/work

Street address

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farbabi@razi.tums.ac.ir

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of dentistry

Full name of responsible person

Fateme Arbabi-Kalati

Position

spacialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Web page address

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