

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation of the Effectiveness of Crocin of Saffron in treatment of Burning Mouth Syndrome

#### Protocol summary

##### Study aim

Determination of the Effectiveness of Crocinic Saffron in Treatment of Burning Mouth Syndrome

##### Design

A double-blind, parallel randomized clinical trial (phase III) for 50 patients has been designed.

##### Settings and conduct

This double-blind randomized clinical trial is conducted at Mashhad Dental School, Iran. Participants and care providers and assessing outcomes and the statistician are blinded to the type of drug because drugs are placed in similar seal envelope packs.

##### Participants/Inclusion and exclusion criteria

The criteria for inclusion of patients in the study included: Daily bilateral burning sensation of oral mucosa for at least 4 to 6 months, persistent or increased burning intensity throughout the day, natural oral mucosa in clinical examination and the absence of any local or systemic causes to legitimize the irritation of the mouth, minimum burning intensity of 5 on the VAS scale for patients with BMS, not receiving any antidepressant treatment during the last 4 weeks . The criteria for excluding patients from the study were: the history of systemic disease characterized by burning mouth including diabetes, severe anemia, hypothyroidism, repetitious reflux or a history of micronutrient deficiency , severe psychological disorders such as severe depression, suicide thoughts and the history of hospitalization in psychiatric hospitals, pregnant patients or ones suspected to be pregnant, reports of any susceptibility to drugs or adverse effects, the use of monoamine oxidase inhibitors, tramadol, beta-blockers, benzodiazepines, tricyclic antidepressants at present or the recent month .

##### Intervention groups

control group:Citalopram (Sobhan Darou, Iran) once Daily.The initial dose is 10 mg and increased to 20 mg after a week. intervention group: 15 mg Crocin tablet (prepared by a pharmacologist colleague) twice daily.

#### Main outcome variables

pain and burning

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180416039318N1**

Registration date: **2018-05-20, 1397/02/30**

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

Last update: **2018-05-20, 1397/02/30**

Update count: **0**

##### Registration date

2018-05-20, 1397/02/30

##### Registrant information

##### Name

Ala Ghazi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3882 9501

##### Email address

ghazial@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-25, 1397/02/05

##### Expected recruitment end date

2018-06-23, 1397/04/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the Effectiveness of Crocin of Saffron in treatment of Burning Mouth Syndrome

**Public title**

Effect of Saffron in treatment of Burning Mouth Syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Daily bilateral burning sensation of oral mucosa for at least 4 to 6 months, persistent or increased burning intensity throughout the day, natural oral mucosa in clinical examination and the absence of any local or systemic causes to legitimize the irritation of the mouth, minimum burning intensity of 5 on the VAS scale for patients with BMS, not receiving any antidepressant treatment during the last 4 weeks

**Exclusion criteria:**

the history of systemic disease characterized by burning mouth including diabetes, severe anemia, hypothyroidism, repetitious reflux or a history of micronutrient deficiency, severe psychological disorders such as severe depression, suicide thoughts and the history of hospitalization in psychiatric hospitals, pregnant patients or ones suspected to be pregnant, reports of any susceptibility to drugs or adverse effects, the use of monoamine oxidase inhibitors, tramadol, beta-blockers, benzodiazepines, tricyclic antidepressants at present or the recent month

**Age**

From **15 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

seal envelope

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the prepared medicine packs are the same for the two groups. Packages are coded from 1 to 40 by an individual outside the study and the mode and duration of consumption are given in the package. Packages are randomly delivered to patients. It should be noted that the psychiatrist, the participants and care providers and assessing outcomes and statistician are

unaware of the type of prescribed medicine.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Mashhad University of Medical Sciences- Research Ethics Committee

**Street address**

Mashhad Dental School, Azadi Square, Vakilabad Blvd

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

911735984

**Approval date**

2015-05-09, 1394/02/19

**Ethics committee reference number**

IR.mums.REC.1394.66

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

Burning Mouth Syndrome

**ICD-10 code**

F59

**ICD-10 code description**

Unspecified behavioural syndromes associated with physiological disturbances and physical factors

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

Burning and pain

**Timepoint**

at baseline and during treatment procedure (intervals of third, seventh and eleventh week after the beginning)

**Method of measurement**

visual analogue scale

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

Depression and anxiety

### Timepoint

1. at baseline and during treatment procedure (intervals of the third, seventh and eleventh week after the beginning)

### Method of measurement

Hamilton questionnaire

## Intervention groups

### 1

#### Description

Intervention group: tablet of Saffron Crocin 15 mg (prepared by a pharmacologist colleague) is prescribed twice daily. Consumption duration is determined to be 11 weeks. The severity of burning, depression, and anxiety of patients are measured and recorded at baseline and intervals of the third, seventh and eleventh week after the beginning.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Citalopram (Sobhan Darou, Iran) is prescribed once daily. The initial dose is 10 mg and increased to 20 mg after a week. Consumption duration is determined to be 11 weeks. The severity of burning, depression, and anxiety of patients are measured and recorded at intervals of the third, seventh and eleventh week after the beginning.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Oral and maxillofacial Diseases Department of Mashhad Dental School

##### Full name of responsible person

Dr. Atessa Pakfetrat

##### Street address

Mashhad Dental School, Azadi Square, Vakilabad Blvd

##### City

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##### Postal code

9177948959

##### Phone

+98 51 3882 9501

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##### Email

pakfetrata@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Mohsen Tafaghodi

##### Street address

Mashhad University of Medical Sciences, Daneshgah St.

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91388-13944

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+98 51 3882 3255

##### Email

tafaghodiM@mums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Roya zamani

##### Position

Associate

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
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Atessa Pakfetrat  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
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assistant  
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ghazial@mums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Some data including demographic properties, signs and symptoms

### When the data will become available and for how long

two months after article publication.

### To whom data/document is available

academic researchers

### Under which criteria data/document could be used

It is permitted to use the data in other studies with reference.

### From where data/document is obtainable

Dr Roya Zamani , ZamaniR921@mums.ac.ir

### What processes are involved for a request to access data/document

sending email to authors. the authors will send data via email during 4 weeks.

### Comments