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

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Mashhad Dental School, Azadi Square, Vakilabad Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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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

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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