Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative effects of matrica extract and Nystatin mouthwash on erytematous denture osteomatitis

Protocol summary

Study aim

Comparative effects of matrica extract and Nystatin mouthwash on erytemarous denture osteomatitis

Design

The clinical trial with the parallel intervention group is one-way, blind, randomized. Our randomization method is simple and our tool for randomization is a random number table. The 22 people will be divided into two groups. The first group will receive matrica mouthwash and the second group will receive nystatin for 20 days. Then the length and width of the erythema in the two groups will be determined and compared in 5-10-15-20 days.

Settings and conduct

Individuals referring to the Oral Diseases Department of the Faculty of Dentistry, University of Tabriz, who suffer from denture stomatitis erythematosus will be selected. The individuals will be divided into two groups and randomly placed in one group. The first group will receive barrage essential oil matrica mouthwash for 20 days and 20 drops three times a day, and the second group will receive nistanin mouthwash according to the conditions of the first group.Participants are not aware of the type of mouthwash.

Participants/Inclusion and exclusion criteria

Entrance criteria: Having denture stomatitis erythematosus , suitable tooth , Mental health Exit criteria: Use of antifungal drugs , antibiotics and corticosteroids in past month, allergy to matrica, Alzheimer's disease, people with neuromuscular diseases, Having granular pin point denture stomatitis, Having mental disabilities, Diabetic patients, Smoking patients

Intervention groups

The 22 people will be divided into two groups. The first group will receive matrica mouthwash and the second group will receive nystatin mouthwash for 20 days.

Main outcome variables

The length of erythema after use of matrica extract and nystatin in 5-10-15-20 days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200218046544N2**
Registration date: **2020-09-05, 1399/06/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-05, 1399/06/15**
Update count: **0**

Registration date

2020-09-05, 1399/06/15

Registrant information

Name

Vahid Fakhrzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 5965

Email address

fakhrzadehv@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-31, 1399/06/10

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative effects of matrica extract and Nystatin mouthwash on erytematous denture osteomatitis

Public title
Comparative effects of matrica extract and Nystatin mouthwash on erytematous denture osteomatitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having denture stomatitis erythematosus Willingness to participate in the study Ability to use mouthwash Suitable tooth (healthy without looseness and discoloration) Mental health

Exclusion criteria:
Use of antifungal drugs Antibiotics and corticosteroids in past month Allergy to matrica Alzheimer's disease people with neuromuscular diseases Having granular pin point denture stomatitis Having mental disabilities Diabetic patients Smoking patients

Age
No age limit

Gender
Both

Phase
1

Groups that have been masked

- Participant

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description
Random sampling method is available among people referring to the Department of Prosthodontics, Tabriz Dental School. The method of randomization is simple and its unit is individual. Our tool is to randomize the table of random numbers. Assignment of mouthwash to patients is also done randomly. In this way, two types of mouthwash were recorded by numbering numbers one and two, then the numbers were placed in a bag and stirred, then one number was randomly taken out of the bag for each patient and the mouthwash was given to them according to the desired number. Neither patient will be informed of their own type of mouthwash and that of another patient.

Blinding (investigator's opinion)
Single blinded

Blinding description
None of the patients are aware of the existence of two types of mouthwash, nor are they aware of their own type of mouthwash and that of another patient.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Floor2, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Approval date
2020-06-28, 1399/04/08

Ethics committee reference number
IR.TBZMED.REC.1399.408

Health conditions studied

1

Description of health condition studied
Denture Stomatitis

ICD-10 code
K12.1

ICD-10 code description
Other forms of stomatitis

Primary outcomes

1

Description
The length of erythema

Timepoint
Before starting the use of mouthwash (day=0) and 5, 10, 15, 20 days after starting the mouthwash

Method of measurement
It will be measured by a digital calibrated caliper (made in Germany) and recorded in hundredths of a millimeter.

Secondary outcomes

1

Description
Width of erythema

Timepoint
Before starting the use of mouthwash(day= zero) and 5, 10, 15, 20 days after using

Method of measurement
It will be measured by a digital calibrated caliper (made in Germany) and recorded in hundredths of a millimeter.

Intervention groups

1

Description
Intervention group1: 11 people in this group are prescribed matrica mouthwash and the patient will be told to rinse 20 drops of the drug 3 times a day, once every 8 hours and each time for 60 seconds. After each use of mouthwash, put the denture in your mouth and avoid eating and drinking for 30 minutes.
Category
Treatment - Drugs

2

Description
Intervention group2: People in this group will be prescribed nystatin mouthwash produced by Jaber Binuhian Pharmaceutical Company (Tehran, Iran). Slowly After each use of mouthwash, put the denture in your mouth and avoid eating and drinking for 30 minutes.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz University of Medical Sciences, Dentistry Faculty, Department of Prosthodontics
Full name of responsible person
Dr Vahid Fakhrzadeh
Street address
Floor2, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad samiei
Street address
Floor2, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St.
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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
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Tabriz University of Medical Sciences
Full name of responsible person
Dr Vahid Fakhrzadeh
Position
Assistant professor of Prosthodontics
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Floor2, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St.
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Email
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person

Dr Vahid Fakhrzadeh

Position
Assistant professor of Prosthodontics

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available