Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the therapeutic effect of mouthwash containing sumac extract and nystatin suspension in patients with denture stomatitis

Protocol summary

Study aim

-Determining the size of denture stomatitis lesions and number of Candida albicans colonies before and after using Sumac and nystatin mouthwashes, -Determining the correlation between sex parameter and number of Candida albicans colonies, -Determining the correlation between sex parameters and size of denture stomatitis lesions.

Design

A clinical trial with a control group, with parallel, double-blind, randomized groups, will be performed on 22 patients.

Settings and conduct

This study will be performed as a double-blind clinical trial on patients referred to the Clinic of Sari Dental School (Mazandaran-Iran) in two groups of 11 people (control and intervention group). Patients and examiners and therapists will not be aware of the type of drug used and the type of study group.

Participants/Inclusion and exclusion criteria

Patients with complete maxillary dentures with denture Stomatitis referred to Sari Dental clinic are examined. Patients with a history of antifungal drugs, antibiotics, and corticosteroids in a recent month, nystatin mouthwash allergy, immunocompromised patients, Alzheimer's, psychological disorders, chewing muscle disorder, inability to use mouthwash, and patients with loose dentures and discoloration will be excluded.

Intervention groups

Sumac and nystatin mouthwashes are given in 2 identical containers (in shape, size, and color). Nystatin 100000u/ml mouthwash and Sumac mouthwash will be gargled 3 times a day (20 drops each time). Patients are asked to hold the mouthwash in their mouth for 1 minute and to avoid eating and drinking for at least 1 hour after using the mouthwash. Treatment will continue for 2 weeks and erythematous lesions will be checked weekly.

Main outcome variables

In this study, the effect of using mouthwash containing sumac extract in the treatment of denture stomatitis will be compared with nystatin mouthwash.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210429051121N1**
Registration date: **2021-11-29, 1400/09/08**
Registration timing: **retrospective**

Last update: **2021-11-29, 1400/09/08**
Update count: **0**

Registration date

2021-11-29, 1400/09/08

Registrant information

Name
Ali Malekzadeh Shafaroudi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-27, 1400/07/05

Expected recruitment end date

2021-10-12, 1400/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the therapeutic effect of mouthwash containing sumac extract and nystatin suspension in patients with denture stomatitis

Public title
Evaluation of the effect of a mouthwash containing sumac extract on patients with denture stomatitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients referred to the clinic of Sari Dental School due to maxillary complete denture Patients with denture stomatitis (type II and III) with confirmation of denture stomatitis in patients by an oral pathologist

Exclusion criteria:
Patients with a history of using antifungal drugs, antibiotics and corticosteroids in a last month, Allergy to nystatin mouthwash, Patients with immunodeficiency, Alzheimer's, psychological disorders, chewing muscle disorder, Patients with inability to use mouthwash and patients with loose and discolored dentures,

Age
No age limit

Gender
Both

Phase
0

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **22**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, participants will be randomly assigned to two groups using the Balanced Block Randomization. From 6 possible modes for 4 blocks including two participant from the intervention group and two participant from the control group using the RANDBETWEEN command in Excel software, 6 blocks will be selected randomly and a random sequence will be created. According to the random sequence, Participants will be divided into intervention and control groups. Randomization will be performed by the statistics consultant. Also, random sequences concealment for each participant will be done by the supervising dentist.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a randomized double blind clinical trial and patients and examiners and therapists will not be aware of the type of drug used and the type of study group.

Placebo
Not used

Assignment
Parallel

Other design features
In this study, individuals with complete maxillary denture with denture stomatitis (type II and III) referred to the Clinic of Sari Dental School are examined. First, the presence of denture stomatitis in patients is confirmed by an oral specialist, and then, if the patient wishes and the consent form are signed, patients will enter the study. In addition, patients do not know which treatment group they belong to and will be randomly assigned to two groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences

Street address
Vice-Chancellor of Research, Mazandaran University of Medical Sciences, Moallem Square, Sari, Mazandaran, Iran.

City
Sar

Province
Mazandaran

Postal code
4818813965

Approval date
2017-06-25, 1396/04/04

Ethics committee reference number
IR.MAZUMS.REC.1996.2883

Health conditions studied

1

Description of health condition studied
Denture stomatitis - severe palate infection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Size of denture stomatitis lesions before and after using Sumac mouthwash and nystatin mouthwash

Timepoint
Patients are asked to hold the mouthwash in their mouth for 1 minute and to avoid eating and drinking for at least 1 hour after using the mouthwash. Treatment will continue for 2 weeks and erythematous lesions will be checked weekly.

Method of measurement

The length and width of erythematous lesions in the area under the denture are assessed by a calliper and by a specialist on a centimeter basis. Photographic waste will also be prepared each week. At the beginning and end of the study, smear and culture (Sabouraud's dextrose agar) will be prepared from the infected area of the palate. Patients and examiners will not be aware of the type of drug used and the type of study group. In physiological serum in a numbered test tube, the lesion surface was sampled. Then, saliva and plaque samples were immediately transferred to the specialized laboratory of Mazandaran Science and Technology Park for mushroom cultivation and immediately cultured in Saburodextrose agar solid medium next to the flame and under the hood.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Sumac mouthwash will be gargled 3 times a day (20 drops each time)

Category

Treatment - Drugs

2

Description

Control group: Nystatin 100000u / ml mouthwash will be gargled 3 times a day (20 drops each time).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental Clinic of Sari Dental School (Tooba)
Full name of responsible person
Maede Salehi
Street address
Touba Dental Clinic, Khazar Boulevard, Sari, Mazandaran, Iran.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Maede Salehi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
After the publication of the article from the present clinical trial, all information will be available as long as the identities of the study participants remain confidential.

When the data will become available and for how long
After completing the phases of the clinical trial and publishing the article resulting from this clinical trial in a journal, information will be available to all eligible individuals.

To whom data/document is available
All researchers from a reputable scientific organization can request information.

Under which criteria data/document could be used
All researchers from a reputable scientific organization can request information.

From where data/document is obtainable
Applicants can request more information via e-mail with Dr. Maedeh Salehi.

What processes are involved for a request to access data/document
All applicants must have valid documents of cooperation with reputable organizations and universities of medical sciences and submit them to Dr. Maedeh Salehi. Then their request will be reviewed and if the documents are valid, they will cooperate.

Comments