Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Investigating and comparing the effect of combined herbal mouthwash (containing thyme, mord, licorice and aloe vera) and nystatin on Denture stomatitis; A three-blind randomized clinical trial study

Protocol summary

Study aim

Using a completely herbal mouthwash with anti-fungal and anti-inflammatory properties..., with less side effects for patients with denture stomatitis

Design

Clinical trial with two control and intervention groups, three blind strains, randomized by Balance block randomization , phase 2 on 48 patients

Settings and conduct

DS patients referred to Qazvin univercity Patients are entered into the study with personal consent, then the information related to age, gender, duration of denture use, daily number of mouth and denture cleaning cases, as well as burning sensation and pain in the area are recorded. The dimensions of the erythema in time Entry is measured in mm. Patients are randomly divided into control and intervention groups. In the intervention group, herbal mouthwash is given to the patient and in the control group, nystatin (both mouthwashes are in the same bottles)to gargle 3 times a day for 3-5 minutes for 14 days, one cup each time. Also, in both groups, people were taught to clean their dentures daily .On the 1st, 7th and 14th days, the samples are examined in terms of the size of the existing lesions and the degree of pain and burning sensation.ahso, on the 7th and 14th days, the patient is also asked about the satisfaction with the taste of the medicine.

Participants/Inclusion and exclusion criteria

Inclusion: People who volunteer to participate in the study. Patients with Denture Stomatitis lesions in the active phase Exclusion: Improper prosthesis Suffering from systemic and autoimmune diseases such as diabetes, blood pressure, etc. The patients' use of any type of medicine that affects the quality and quantity of saliva

Intervention groups

Control: Nystatin intervention: herbal mouthwash

Main outcome variables

The size of the lesion, the amount of pain and burning sensation in the mouth, and the satisfaction with the taste of the medicine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240406061421N1**
Registration date: **2024-04-15, 1403/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2024-04-15, 1403/01/27**
Update count: **0**

Registration date

2024-04-15, 1403/01/27

Registrant information

Name

Fateme Rahmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 910 192 4167

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-15, 1403/01/27

Expected recruitment end date

2024-06-16, 1403/03/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating and comparing the effect of combined herbal mouthwash (containing thyme, mord, licorice and aloe vera) and nystatin on Denture stomatitis; A three-blind randomized clinical trial study

Public title

Investigating and comparing the effect of combined herbal mouthwash (containing thyme, mord, licorice and aloe vera) and nystatin on Denture stomatitis

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

People who volunteer to participate in the study Patients with denture stomatitis lesions in the active phase (diagnostic criteria are swelling and inflammation below the surface of the prosthesis) who are clinically confirmed by two specialists in oral diseases.

Exclusion criteria:

Improper prosthesis Suffering from systemic and autoimmune diseases such as diabetes, blood pressure, etc. The patients' use of any type of medicine that affects the quality and quantity of saliva

Age

From **20 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are allocated to two treatment groups A and B using the Balance block randomization method, the size of each block is 8 and the total number of blocks is 6. Balanced randomization allocation method for the participants in the clinical trial study of the effect of receiving nystatin and mouthwash It is a plant that improves DS.

Blinding (investigator's opinion)

Triple blinded

Blinding description

After filling the informed consent form and information on how to carry out the plan, patients receive a mouthwash (herbal or nystatin in similar bottles) Mouthwashes are given to patients by person A, and all sizes are evaluated by person B The data analyst does not know which mouthwash was used in each group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Bahonar Blv

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2024-03-18, 1402/12/28

Ethics committee reference number

IR.QUMS.REC.1402.414

Health conditions studied

1

Description of health condition studied

Denture stomatitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Dimensions of the lesion

Timepoint

The first, seventh and fourteenth days from the time of entering the study

Method of measurement

Caliper in mm

Secondary outcomes

1

Description

Burning and pain

Timepoint

The first, seventh and fourteenth days from the time of entering the study

Method of measurement
VAS

2

Description
Pain
Timepoint
The first, seventh and fourteenth days from the time of entering the study
Method of measurement
VAS

Intervention groups

1

Description
Intervention group: patients who receive herbal mouthwash
Category
Treatment - Drugs

2

Description
Control group: patients receiving nystatin
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin University of Medical Sciences
Full name of responsible person
Fateme rahmani
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Sponsors / Funding sources

1

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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
Qazvin University of Medical Sciences
Proportion provided by this source
30
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
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Fatemeh Rahmani
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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
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
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Changes in lesion dimensions will be recorded and published during the study
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
Every body
Under which criteria data/document could be used
Treatment of dental stomatitis
From where data/document is obtainable
The person responsible for updating information
What processes are involved for a request to access data/document
Action by email Respond as soon as possible
Comments