Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Mucosal Micro-needling for Nystatin Delivery in the Treatment of Denture Stomatitis- A Randomized Clinical Trial

Protocol summary

Study aim

In this study, the effect of mucosal microneedling to transfer nystatin in the treatment of denture stomatitis is investigated

Design

This research is a randomized clinical trial study on 10 patients who have macular erythematous in the palatal area and have referred to the oral diseases department of the dental faculty. In each patient, one of the left or right side of the lesion is selected as the intervention area and the other side as the control area .For randomization from 10 separate cards It was used with two options, right or left.

Settings and conduct

Patients referring to Semnan Dental Faculty are taught to place and hold the microneedle on a randomly selected side for one minute, and then use nystatin suspension (two full drips each time for two minutes, 3 times a day). to use And after 5 and 10 days, go to the dentist for follow-up. The final year student, who has passed the criteria for diagnosing lesions and received practical training, examines the samples according to the severity of the existing lesions based on the clinical examination method. In this way, the patient's mouth is examined and recorded for the presence or absence of denture stomatitis and its severity (0 absence of denture stomatitis, 1 mild redness, 2 moderate to severe redness, and 3 granular level).

Participants/Inclusion and exclusion criteria

Inclusion criteria :They use complete and partial upper jaw dentures Exclusion criteria :Smoking and drug addiction .History of allergy to antifungals such as nystatin

Intervention groups

People who have a 2-cm-wide denture stomatitis lesion were selected and the lesion was divided into two parts, and in each patient, one of the left or right side of the lesion in the palate was selected as the intervention area and the other side as the control area with an allocation ratio of 1:1.

Main outcome variables

The effect of microneedle on the intensity of the lesion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231209060307N2**
Registration date: **2024-12-12, 1403/09/22**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-12, 1403/09/22**
Update count: **0**

Registration date

2024-12-12, 1403/09/22

Registrant information

Name

Amirhosein Moghaddasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3522 6200

Email address

amirhoosh1378@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-30, 1403/09/10

Expected recruitment end date

2025-02-28, 1403/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Mucosal Micro-needling for Nystatin Delivery in the Treatment of Denture Stomatitis- A Randomized Clinical Trial

Public title

The Effect of Mucosal Micro-needling for Nystatin Delivery in the Treatment of Denture Stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Have informed consent to participate in the study. They use complete and partial upper jaw dentures. People who have bilateral involvement of the lesion with a width of at least 2 cm.

Exclusion criteria:

Addiction to cigarettes and drugs History of allergy to antifungals such as nystatin Pregnant or lactating people Volunteers who have adverse drug reactions (such as an allergic reaction to any drug) Patients with uncontrolled systemic diseases

Age

From **25 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

This research is a randomized clinical trial study on 10 patients who have macular erythematous in the palatal region and have referred to the department of oral diseases of the Faculty of Dentistry with complaints of burning in this part of their mouth, and they were diagnosed with Denture stomatitis by an oral disease specialist in It is considered, it is done. In each patient, one of the left or right side of the lesion is selected as the intervention area and the other side as the control area with a ratio of 1:1. To randomize the sides, 10 cards were prepared with two different options written on them: in 5 cards, the right side was considered as the intervention and the left side was considered as the control, and in the other 5 cards, the left side was considered as the intervention and side Right is defined as control. These cards are placed in separate envelopes and when each patient enters, the ward nurse assigns one of the envelopes to him. The envelopes are randomly distributed from the box prepared for this purpose, so that the allocations are completely random, the envelopes are removed from the box after the selection).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Semnan University Of Medical Sciences and Health Services

Street address

17 Shahrivar St

City

Semnan

Province

Semnan

Postal code

3671674569

Approval date

2024-10-14, 1403/07/23

Ethics committee reference number

IR.SEMUMS.REC.1403.199

Health conditions studied

1

Description of health condition studied

Denture stomatitis

ICD-10 code

B37.0

ICD-10 code description

Candidal stomatitis

Primary outcomes

1

Description

Healing the lesion caused by the denture

Timepoint

At the beginning of the study and after 5 and 10 days

Method of measurement

By visual inspection (0- Absence of denture stomatitis 1- mild redness 2-moderate to severe redness 3-granular surface)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Part of the lesion in the palate where microneedle is applied and nystatin mouthwash is given .The patient is taught to place and hold the microneedle on a randomly selected side for one minute and then use nystatin suspension (Two full droppers at each turn for two minutes 3 times a day).The microneedling used in this study has a height of 600, a base of 300 and a distance between the needles of 500 micrometers. have been made.

Category
Treatment - Devices

2

Description
Control group: Part of the lesion in the palate where only nystatin mouthwash is given.(Two full droppers at each turn for two minutes 3 times a day)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of Dentistry, Semnan University of Medical Sciences

Full name of responsible person
Nahid Karbasi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Maryam Jalili

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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
Semnan 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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Nahid Karbasi

Position
Assistant professor

Latest degree
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Other areas of specialty/work
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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
Yes - There is a plan to make this available
Title and more details about the data/document
All the data obtained from the participants will be shared under the title of Microneedling plan patients
When the data will become available and for how long
After 6 months, the results will be printed
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Any kind of qualitative and quantitative analysis on the data for research work by the researchers in this field is unobstructed
From where data/document is obtainable
Dr. Nahid Karbasi -Semnan Faculty of Dentistry
What processes are involved for a request to access data/document
After sending the application by e-mail and reviewing the researcher's resume, the documents will be sent to the individual within 6 months.
Comments