

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Effectiveness of Ozone Containing paste and Nystatin paste Sseverity of Denture Stomatitis among Denture wearer patients

Protocol summary

Study aim

1.Determining the severity of denture stomatitis in the group using ozone-containing paste on the first and fifteenth. 2.Determination of denture stomatitis severity in the group using nystatin on the first and fifteenth days. Comparison of two groups in terms of denture stomatitis severity in the first and fifteenth days.

Design

This study was performed as an experimental, single-blind clinical trial. Patients were randomly divided into two groups using hexagonal blocks. One group received ozone paste and the other group (control) received nystatin. To determine the sample size, first in a pilot study, 30 people from each group were included in the study. After collecting the data, using it, the sample size was estimated and the study continued until the calculated sample number was reached.

Settings and conduct

This study was performed as an experimental, single-blind clinical trial. These patients were divided into two groups. Visits took place on the first, seventh and fifteenth days. The drugs delivered to patients in both groups had the same packaging. Then the drug and method of use were given to the patient. The research site was Semnan dental clinics.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients using denture with stomatitis denture lesions in the palate. Conditions of non-entry: denture with poor compliance. Prohibition of prescribing ozone. Prohibition of prescribing nystatin.

Intervention groups

Ozone paste was delivered to patients as a tube for two weeks for the case group. Nystatin (purchased from products of Jabraban Hayan Pharmaceutical Company) was given as an ointment to patients in the control group for one week.

Main outcome variables

Do not use nystatin and ozone paste.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201026049146N1**

Registration date: **2021-01-04, 1399/10/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-04, 1399/10/15**

Update count: **0**

Registration date

2021-01-04, 1399/10/15

Registrant information

Name

Sajad Karajian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4335 3422

Email address

sajadkarajian11@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effectiveness of Ozone Containing paste and Nystatin paste Sseverity of Denture Stomatitis among Denture wearer patients

Public title

Comparison of Effectiveness of Ozone Containing paste and Nystatin paste Sseverity of Denture Stomatitis among Denture wearer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 40 to 80 years old using Denture with Denture lesions of the Stomatitis in the palate

Exclusion criteria:

Denture with poor compliance Prohibition of prescribing ozone Prohibition of prescribing nystatin

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization, Individual, Random Number Tables. Randomized permutation blocks (block 6). Using Excel software to generate random number tables

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are unaware of the allocation of study groups. Ozone and nystatin paste were given to patients in similar packages and patients were unaware of the allocation to study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

17 Shahrivar Blvd. Semnan Dental School

City

Semnan

Province

Semnan

Postal code

3518794431

Approval date

2020-08-25, 1399/06/04

Ethics committee reference number

IR.SEMUMS.REC.1399.173

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

Patients with denture stomatitis

Timepoint

Measurement of denture stomatitis severity in the first and fifteenth days

Method of measurement

Examination form for patients with denture stomatitis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ozone paste was delivered to patients as a tube for two weeks for the case group. The ozone group placed the ozone paste in the maxilla denture 4 times daily after each meal after cleaning the denture with a toothbrush, and the denture did not come out until the next meal.

Category

Treatment - Drugs

2

Description

Control group: Nystatin was given as an ointment to patients in the control group for one week. In the nystatin group, the ointment was used 4 times a day according to the instructions.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan Dental School

Full name of responsible person

Sajad Karajian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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Basij Blvd, Semnan

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Sajad Karajian

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Sajad Karajian

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available