Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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
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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?
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
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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Latest degree
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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