

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

comparison of clinical and microbiological efficacy of nystatin suspension in the management of denture stomatitis

Protocol summary

Study aim

Comparison of clinical and microbiological effect of nystatin suspension on denture stomatitis treatment

Design

a clinical trial with a control group, one blind, nonrandomization

Settings and conduct

Patients referred to the Oral Diseases Department of Beheshti University and patients in Tehran nursing homes who use complete denture and maxillary partial and they have type II denture stomatitis and are in accordance with the mentioned input and output criteria after obtaining the consent, they will enter the study. In order to clinically evaluate patients with a cotton swab from the patients' palate before prescribing the drug to determine the number of Candida colonies will be performed. For achieve a criterion for defining the normal amount of Candida colony in the mouth of people without denture stomatitis, sampling of their palate will be done. Patients are given 30 drops of nystatin suspension 4 times a day. The cotton swab is placed in a Falcon tube containing 1% CC normal saline. After vortex, the tube is inoculated with 10 µl of the contents of the tube into Candida chrome agar. The samples will then be sent for culture of the candidate and counting the number of colony units. Patients will be followed up on the 14th day after drug administration and on the 21st and 28th day after drug administration. They will be sampled again with a swab to count the number of colony units and previous steps will be repeated

Participants/Inclusion and exclusion criteria

Denture stomatitis type II based on Newton classification (:) Patients diagnosed with diabetes, anemia, immunosuppression, cancer treatment (radiotherapy and chemotherapy)

Intervention groups

achieve a safer duration of recovery (clinical and microbiological) for the treatment of denture stomatitis and the effectiveness of nystatin suspension

Main outcome variables

candida count; candida albicans count; remission time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049173N1**

Registration date: **2020-12-02, 1399/09/12**

Registration timing: **prospective**

Last update: **2020-12-02, 1399/09/12**

Update count: **0**

Registration date

2020-12-02, 1399/09/12

Registrant information

Name

Parisa Hajighasem

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2217 5351

Email address

ib.hajighasem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-05, 1399/09/15

Expected recruitment end date

2021-02-03, 1399/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of clinical and microbiological efficacy of nystatin suspension in the management of denture stomatitis

Public title

clinical and microbiological efficacy of nystatin suspension in the management of denture stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Denture stomatitis type II based on Newton classification use complete denture of maxilla partial class I (Bilateral edentulous areas with no teeth behind them) At least for a year Do not take any antifungal drugs associated with fungal infections Having general health Patient satisfaction and cooperation

Exclusion criteria:

Patients diagnosed with diabetes, anemia, immunosuppression, cancer treatment (radiotherapy and chemotherapy) Receiving antifungal medication or antibiotics or steroids in the last 4 weeks People with xerostomia smokers Pregnant and lactating women People who are allergic to azole or polyene groups

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 25

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

School of Dentistry, Shahid Beheshti university of medical sciences, Daneshjoo Blvd, Evin, Chamran high way

City

Tehran

Province

Tehran

Postal code

1983963113 بزرگراه

Approval date

2020-08-25, 1399/06/04

Ethics committee reference number

IR.SBMU.DRC.REC.1399.039

Health conditions studied**1****Description of health condition studied**

denture stomatitis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Total candida count

Timepoint

0,14,21,28

Method of measurement

Microbiological survey

2**Description**

remission time

Timepoint

14,21,28 day

Method of measurement

examination

Secondary outcomes**1****Description**

albicans candida count

Timepoint

0,14,21,28

Method of measurement

microbiological survey

Intervention groups**1****Description**

Intervention group: nystatin suspension 100000

unit/ml,Four times a day in the amount of 30 drops,One minute mouthwash,Until complete recovery,Emad Darman Pars pharmaceutical company

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

dental school of Shahid Beheshti university

Full name of responsible person

Parisa Hajighasem

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School of Dentistry, Shahid Beheshti university of medical sciences, Daneshjoo Blvd, Evin , Chamran high way

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parisa Hajighasem

Position

3 Postgraduate Student of Oral Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Parisa Hajighasem

Position

Post graduate

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available