Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 zerostomia 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
بزرگراه1983963113

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

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Position

Post graduate

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person
Parisa Hajighasem
Position
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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