Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison of antifungal effect of Curcumin and Nystatin in denture stomatitis type 2 and type 3

Protocol summary

Study aim
Comparison effect of anti fungal therapy with curcumin and nystatin in denture stomatitis in Islamic Azad University of Tehran- school of Dentistry

Design
Randomized clinical trial, parallel group, single blind, without placebo

Settings and conduct
in patients who refer to Oral Medicine department of school of Dentistry-Islamic Azad University of Tehran who have type 2 and 3 denture stomatitis first erythema and colony forming unit (CFU) of Candida albicans of patient palate are recorded before treatment. Then patients are randomly divided into two groups of 16 : one group is given nystatin and curcumin, and the other group is given nystatin, and after treatment, erythema and CFU Candida albicans are re-registered..

Participants/Inclusion and exclusion criteria
Inclusion criteria:patients above 18; with Denture stomatitis; type 2 and 3 Exclusion criteria: patients with allergy to curcumin ; pregnant ;breast feeding women; changes in immune system; chemotherapy; radiotherapy; patients who take antibiotics and anti fungal drugs within 4 weeks ago

Intervention groups
Intervention group: The effective ingredient of curcumin in aqueous solvent prepared orally Control group: Nystatin suspension 100,000 units per milliliter of Emad Company

Main outcome variables
Comparison of treatment result in 2 groups - Decreased number of candida albicans and decreased erythema

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200519047516N1**
Registration date: **2020-07-24, 1399/05/03**
Registration timing: **prospective**

Last update: **2020-07-24, 1399/05/03**
Update count: **0**

Registration date
2020-07-24, 1399/05/03

Registrant information

Name
Haniye Meftahpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8863 9044

Email address
haniye.meftahpour@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-06, 1399/07/15

Expected recruitment end date
2021-06-21, 1400/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of antifungal effect of Curcumin and Nystatin in denture stomatitis type 2 and type 3

Public title
Comparison of the antifungal effect of Curcumin and Nystatin in treatment of fungous associated with

removable prothesis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients above 18 With denture stomatitis; type 2 and 3

Exclusion criteria:

Exclusion criteria: patients with allergy to curcumin pregnant breast feeding women changes in immune system chemotherapy radiotherapy patients who take antibiotics and anti fungal drugs within 4 weeks ago

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients will have two types of denture stomatitis 2 and 3, and to prevent the accumulation of a type of denturestomatitis in a group and its negative impact on the results, the Stratified block randomized method will be used and 32 envelopes are numbered by statistical consultant and the interventions are given to the patients without the knowledge of the researcher of the contents of the envelopes containing the therapeutic intervention and the researcher will not be aware of the contents of the envelope and the intervention made for each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, after informing the patient of the type of study, and filling out the drug consent form with the help of another person other than the researcher and according to the random numbers determined by the statistical consultant (2 series No. 1 to 16 for Dentuer Stomatitis Type 2 and 3) It will be given to patients

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

IslamicEthic committe of Islamic Azad university - Dental branch Tehran - Iran

Street address

10th Neyestan- Pasdaran avenue- Tehran

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2020-05-09, 1399/02/20

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.007

Health conditions studied

1

Description of health condition studied

Denture stomatitis

ICD-10 code

B37

ICD-10 code description

Candidiasis

Primary outcomes

1

Description

Count of cloni

Timepoint

Before intervention-2 weeks after intervention

Method of measurement

Colony forming unit (CFU) with microbiological measurment

2

Description

Erythema

Timepoint

Before intervention-2 weeks after intervention

Method of measurement

mm2- measured in photoshop program

Secondary outcomes

1

Description

Erythema

Timepoint

before intervention

Method of measurement

Measurement in millimeters

2

Description
Number of Candida albicans colonies
Timepoint
before intervention
Method of measurement
Prepare culture from the patient's mouth and count the number of colonies

Intervention groups

1

Description
Intervention group: drug(Curcumin drops prepared from the active ingredient of curcumin in the pharmacology department of the Faculty of Pharmacy, Islamic Azad University-5 cc -4 times in day for 2 weeks- wash the mouth)
Category
Treatment - Drugs

2

Description
Control group: standard drug(Nyststin suspension100000 unit/ml emad company- 40 drops-4 times in day for 2 weeks- wash the mouth)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Azad Islamic University of Tehran-school of Dentistry-Oral Medicine department
Full name of responsible person
Haniye Meftahpour(Oral Medicine assistant)
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Pofessor: Dr Arash Azizi
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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
Islamic Azad University
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
Islamic Azad University
Full name of responsible person
Haniye Meftahpour
Position
Doctor Dentist Surgon/ assistant of Oral Medicin
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Name of organization / entity
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Position
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Person responsible for updating data

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Web page address

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