

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparing effect of anti fungal therapy with Zataria Multi Flora and Nystatin in the treatment of patients with Denture stomatitis type 2 and type 3

Protocol summary

Summary

purpose of study:comparison effect of anti fungal therapy with Zataria Multi Flora and Nystatin in Denture stomatitis in Islamic Azad University of Tehran- school of Dentistry in 2017-2018 design of study: randomised, single blind, without placebo, single center population of study:patients who refer to Oral Medicine department of school of Dentistry-Islamic Azad University of Tehran Inclusion criteria:patients above 18; with Denture stomatitis; type 2 and 3 Exclusion criteria: patients with Renal disease; Liver disease; Thyroid disease; Diabete; Xerostomia ; hypo parathyroidism; pregnant ;breast feeding women; changes in immune system; chemotherapy; radiotherapy; patients who take antibiotics and anti fungal drugs within 4 weeks ago 28 patients intervention : measurement of erythem and CFU of Candida Albicans before intervention. then dividing patients in 2 groups randomisly. one group take Nyststin and another group take Zataria Multi Flora. after treatment measuring erythem and CFU of Candida Albicans of palate again . time of intervention :2 weeks comparison of treatment result in 2 groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061834619N1**
Registration date: **2017-09-24, 1396/07/02**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-24, 1396/07/02

Registrant information

Name

Tarane Farrokhnia

Name of organization / entity

Azad Islamic University of Tehran

Country

Iran (Islamic Republic of)

Phone

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Email address

t_farrokhnia@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Azad Islamic University of Tehran- school of Dentistry/
private

Expected recruitment start date

2017-10-07, 1396/07/15

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of anti fungal therapy with Zataria Multi Flora and Nystatin in the treatment of patients with Denture stomatitis type 2 and type 3

Public title

Comparing effect of anti fungal therapy with Zataria Multi Flora 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: patients with Renal disease; Liver disease; Thyroid disease; Diabet; Xerostomia; hypoparathyroidism; pregnant; breast feeding women; changes in immune system; chemotherapy; radiotherapy; patients who take antibiotics and antifungal drugs within 4 weeks ago

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 28

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Islamic Azad University of Tehran- school of Dentistry

Street address

10th Neyestan- Pasdaran avenue- Tehran

City

Tehran

Postal code

1946853314

Approval date

2017-03-12, 1395/12/22

Ethics committee reference number

IR.IAU.DENTAL.REC.1395,35

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

CFU with microbiological measurement

2**Description**

erythem

Timepoint

before intervention-2 weeks after intervention

Method of measurement

mm2- with grid

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

how long use removable denture

Timepoint

before intervention

Method of measurement

years-question from patient

2**Description**

type of Denture stomatitis

Timepoint

before intervention

Method of measurement

type 2,3- visual

3**Description**

how clean the removable denture

Timepoint

before intervention

Method of measurement

water/brush/cleaning agent- question from patient

4**Description**

frequency of cleaning removable denture

Timepoint

before intervention

Method of measurement

0/1/2/3 and more than 3 in week- question from patient

5**Description**

remove of removable denture in night

Timepoint

before intervention
Method of measurement
yes/no -question from patient

Intervention groups

1

Description

intervention: drug(Zataria Multi Flora drop-5 cc -4 times
in day for 2 weeks- wash the mouth)

Category

Treatment - Drugs

2

Description

control : standard drug(Nyststin suspension- 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

Elnaz Gonoodi(Oral Medicine assistant)

Street address

10th Neyestan- Pasdaran avenue- Tehran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

private/Azad Islamic University of Tehran-school of
Dentistry

Full name of responsible person

Tarane Farrokhnia

Street address

10th Neyestan- Pasdaran avenue- Tehran

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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

private/Azad Islamic University of Tehran-school of
Dentistry

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Azad Islamic University of Tehran- school of Dentistry

Full name of responsible person

Elnaz Gonoodi

Position

Doctor Dentist Surgon/ assistant of Oral Medicin

Other areas of specialty/work

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Person responsible for scientific inquiries

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Tarane Farrokhnia

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty