Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Nystatin therapy versus before treatment in patients with denture stomatitis: a before-after clinical trial

Protocol summary

Summary

Objectives: To assess the effect of Nystatin therapy versus before treatment in patients with denture stomatitis. Design: a before-after clinical trial. Setting and conduct: The eligible patients with denture stomatitis who will refer to Dentistry School during the study period will be enrolled into the trial. Inclusion criteria: Patients without teeth with complete denture. Exclusion criteria: (a) having diabetes mellitus; (b) having immunodeficiency disorder; (c) history of using antibiotic, immunosuppressive drugs, radiotherapy, steroid, or antifungal drugs; (d) being simultaneously affected with other oral diseases such as gingivitis or periodontitis. Intervention group: Treatment with Nystatin 100,000 U three times a day for 14 days. Control group: In comparison with before intervention. Primary outcome: (a) assessing the salivary level of IL-10 before treatment and 14 days after treatment; (b) assessing the salivary level of TNF-α before treatment and 14 days after treatment. Secondary outcome: Nothing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508019014N73**
Registration date: **2015-08-03, 1394/05/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-08-03, 1394/05/12

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-07-22, 1393/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Nystatin therapy versus before treatment in patients with denture stomatitis: a before-after clinical trial

Public title

Effect of Nystatin therapy versus before treatment in patients with denture stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients without teeth with complete denture. Exclusion criteria: (a) having diabetes mellitus; (b) having immunodeficiency disorder; (c) history of using antibiotic, immunosuppressive drugs, radiotherapy,

steroid, or antifungal drugs; (d) being simultaneously affected with other oral diseases such as gingivitis or periodontitis.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
Randomization: This is a before after trial without randomization. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Postal code
6517838695

Approval date
2014-06-25, 1393/04/04

Ethics committee reference number
D/P/16/35/9/1543

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
Salivary level of IL-10

Timepoint
Before treatment and 14 days after treatment

Method of measurement
Laboratory test

2

Description
Salivary level of TNF-α

Timepoint
Before treatment and 14 days after treatment

Method of measurement
Laboratory test

Secondary outcomes

empty

Intervention groups

1

Description
Treatment with Nystatin 100,000 U three times a day for 14 days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Dentistry

Full name of responsible person
Dr Masoud Rashizadeh

Street address
School of Dentistry, Hamadan University of Medical Sciences, Shahid fahmideh Ave.

City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Full name of responsible person
Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

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
School of Dentistry

Full name of responsible person
Dr Masoud Rashizadeh

Position
Resident of Dentistry

Other areas of specialty/work

Street address
School of Dentistry, Hamadan University of Medical Sciences, Shahid fahmideh Ave.

City
Hamadan

Postal code

Phone
+98 81 3838 1086

Fax

Email
rashidzadeh2007@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
School of Dentistry

Full name of responsible person
Dr Poorandokht Davodi

Position
Specialist in Oral Diseases

Other areas of specialty/work

Street address
School of Dentistry, Hamadan University of Medical Sciences, Shahid fahmideh Ave.

City
Hamadan

Postal code

Phone
+98 81 3838 1086

Fax

Email
p.davodi@umsha.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Department of Epidemiology

Full name of responsible person
Dr Jalal Poorolajal

Position
Associate Professor

Other areas of specialty/work

Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0090

Fax

Email
poorolajal@umsha.ac.ir

Web page address

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