Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

Effect of Zataria Multiflora (Shirazi Thyme) drop versus Nystatine drop on clinical signs and symptoms in patients with denture stomatitis: a triple blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of Zataria Multiflora (Shirazi Thyme) drop versus Nystatine drop on clinical signs and symptoms in patients with denture stomatitis. Design: a triple blind randomized clinical trial. Setting and conduct: The eligible patients with denture stomatitis, who will refer to Department of Oral Diseases of the School of Dentistry, Hamadan University of Medical Sciences during the study period, will be enrolled into the trial. Inclusion criteria: (a) affected with denture stomatitis type 2 or 3 for at least 11 years; (b) age of 45 to 80 years. Exclusion criteria: (a) sensitivity to Zataria Multiflora or Nystatine; (b) pregnancy; (c) having anemia or malnutrition; (d) having liver disorder, renal diseases, diabetes, xerostomia, hypoparathyroidism, or immunodeficiency; (e) being treated with chemotherapy, antibiotic, or anti-fungal medications. Intervention group: Zataria Multiflora (Shirazi Thyme) drop 0.1%, 2.5 ml 4 times a day for 2 weeks. Control group: Nystatine drop 2.5 ml 4 times a day for 2 weeks. Primary outcome: Assessing the extent of the inflammation and the number of colonies on palate and mucosal surface of the denture stomatitis before treatment and 2, 3, 4 weeks after treatment through physical examination. Secondary outcome: Nothing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507259014N72**
Registration date: **2015-08-01, 1394/05/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-08-01, 1394/05/10

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-03-19, 1393/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Zataria Multiflora (Shirazi Thyme) drop versus Nystatine drop on clinical signs and symptoms in patients with denture stomatitis: a triple blind randomized clinical trial

Public title

Effect of Zataria Multiflora (Shirazi Thyme) drop versus

Nystatine drop on clinical signs and symptoms in patients with denture stomatitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: (a) affected with denture stomatitis type 2 or 3 for at least 11 years; (b) age of 45 to 80 years. Exclusion criteria: (a) sensitivity to Zataria Multiflora or Nystatine; (b) pregnancy; (c) having anemia or malnutrition; (d) having liver disorder, renal diseases, diabetes, xerostomia, hypoparathyroidism, or immunodeficiency; (e) being treated with chemotherapy, antibiotic, or anti-fungal medications.

Age
From **45 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization: Random assignment of the patients to the intervention and control groups one at a time. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

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

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Hamadan

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6517838695

Approval date
2015-04-11, 1394/01/22

Ethics committee reference number
IR.UMSHA.REC.1394.22

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
Assessing the extent of the inflammation and the number of colonies on palate and mucosal surface of the denture stomatitis

Timepoint
before treatment and 2, 3, 4 weeks after treatment

Method of measurement
through physical examination

Secondary outcomes

1

Description
Nothing

Timepoint
Nothing

Method of measurement
Nothing

Intervention groups

1

Description
Zataria Multiflora (Shirazi Thyme) drop 0.1%, 2.5 ml 4 times a day for 2 weeks

Category
Treatment - Drugs

2

Description
Nystatine drop 2.5 ml 4 times a day for 2 weeks

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Dentistry
Full name of responsible person
Dr Zahra Hayati
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School of Dentistry, Hamadan University of Medical Sciences, Shahid fahmideh Ave.
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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
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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
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
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Person responsible for updating data

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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