

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### 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

2014-09-23, 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

##### **City**

Hamadan

##### **Postal code**

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

**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 Zahra Hayati

**Position**

Resident of Oral Diseases

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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Dr Hamid Reza Abdolsamadi

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Oral Diseases Specialist

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## 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**

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**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*