

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Evaluation of Clinical effects of chitosan solution in the treatment of denture stomatitis in the patients refer to the dental clinics of kerman

#### Protocol summary

##### Summary

This study is the clinical part of chitosan effect in the treatment of fungal infections which is a continuation of laboratory studies and is consistent with the standards of material handling. Forty patients who wear full dentures with denture stomatitis type two, randomly selected by an examiner. Patients shouldn't give history of anti-fungal therapy, medicines that reduce saliva and history of immunosuppressive disease from a month ago. Patients, divided into two equal groups and first group should use mouth wash chitosan 1% four times a day, each time 2 ml, for two minutes until two weeks. Another group should use Nystatin as exactly the same way. Palatal smear from infected areas will be obtained, four samples from each patient before and after treatment. Patient will be physically examined in three stages (pre-treatment, one week later and after treatment) and will take photography. The samples will be analyzed mycologically. Mucous form, usually caused by denture stomatitis and blastospore form can be seen at the normal palatal mucosa. Accordingly, palatal smear containing mycelium, also based on clinical signs of infection, lack of erythematous areas mean healing, reduce erythematous areas mean relative improvement and no change means no improvement. Also, the patient's pain is a factor to assess recovery and the patient will be checked by completing the form Visual Analog Scale.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015071223169N1**

Registration date: **2015-08-08, 1394/05/17**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-08-08, 1394/05/17

##### Registrant information

###### Name

Negar Salehi

###### Name of organization / entity

Department of Oral Medicine of Kerman Dental School

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3211 9023

###### Email address

n.salehi@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research center of Oral Medicine of Kerman Dental School

##### Expected recruitment start date

2015-06-21, 1394/03/31

##### Expected recruitment end date

2016-04-19, 1395/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Clinical effects of chitosan solution in the treatment of denture stomatitis in the patients refer to the dental clinics of kerman

##### Public title

effects of chitosan solution in the treatment of fungal infection due to denture

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: patients who wear full dentures with denture stomatitis type two. exclusion criteria: Patients with experience of antifungal agents ; antibiotics ; corticosteroids ; medications that reduce saliva from a month earlier , and also patients with immunosuppressive diseases ; diabetes; masticatory muscle disorders ; Alzheimer's disease and psychological disorders.

### **Age**

No age limit

### **Gender**

Both

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **40**

### **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**

Ethics committee of Kerman Medical Science university

##### **Street address**

Kerman Medical Science Research center/Tahmasbabad squar/Kermane

##### **City**

Kerman

##### **Postal code**

#### **Approval date**

2015-04-07, 1394/01/18

#### **Ethics committee reference number**

AC.KMU.REC.1394.118

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Oral fungal infection

### **ICD-10 code**

B37.0

### **ICD-10 code description**

Candidal stomatitis

## **Primary outcomes**

### 1

#### **Description**

Biological smear evaluation

#### **Timepoint**

Before intervention/one week after intervention/end of second week after intervention

#### **Method of measurement**

Number of candida colonies

### 2

#### **Description**

Pain

#### **Timepoint**

Every day from start to end of intervention

#### **Method of measurement**

Visual analog scale

### 3

#### **Description**

Clinical evaluation

#### **Timepoint**

Before intervention/one week after intervention/end of second week after intervention

#### **Method of measurement**

lesions diameter (MM)

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Mouthwash solution of 1% chitosan with a molecular mass of 5000 Dalton, 30 drops as mouth wash for two minutes 4 times per day for 14 days

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: rinse solution Nystatin 100,000 UI: 30 drops as mouthwash, 4 times per day for 2 minutes for 14 days.

#### **Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Department of Oral Medicine/Kerman Dental School

**Full name of responsible person**

Dr Negar Salehi

**Street address**

Kerman Dental School/Shafa av.

**City**

Kerman

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Research center of Kerman Dental School

**Full name of responsible person**

Dr Zahra Atai

**Street address**

Department of Oral Medicine of Kerman Dental school/Shafa av.

**City**

Kerman

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research center of Kerman Dental School

**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**

Kerman Dental School

**Full name of responsible person**

Negar Salehi

**Position**

Oral Medicine Resident

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

Kerman Dental School/Shafa av.

**City**

Kerman

**Postal code****Phone**

+98 34 3211 9023

**Fax****Email**

debonair\_n@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Kerman Dental School

**Full name of responsible person**

Dr Zahra Atai

**Position**

Associate Professor of Oral Medicine Department

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

Kerman Dental School/Shafa av.

**City**

Kerman

**Postal code****Phone**

+98 34 3211 9023

**Fax****Email**

z\_atai@kmu.ac.ir

**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Department of Oral Medicine of Kerman Dental School

**Full name of responsible person**

Negar Salehi

**Position**

Oral Medicine Resident

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

Kerman Dental School/Shafa av.

**City**

Kerman

**Postal code****Phone**

+98 34 3211 9023

**Fax****Email**

debonair.n@yahoo.com

**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*