Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 untill 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, wil physical examine in three stages (pre-treatment, one week later and after treatment) and will take photography.The samples will be analyzed mycologicly. Myslyal 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 erythematosus areas mean healing, reduce erythematosus 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)
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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

Ethic 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

Befor intervention/one week after intervention/end of secend week after intervention

Method of measurement

Nomber of candida colonies

2

Description

Pain

Timepoint

Every day from start to end of intervention

Method of measurement

Visual analog scale

3

Description

Clinical evaloation

Timepoint

Befor intervention/one week after intervention/end of secend 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 Schoo/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
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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