

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of antibacterial and antifungal properties of complete denture tissue conditioners with adding chitosan, silver and zinc oxide nanoparticles

Protocol summary

Study aim

The aim of this study was to evaluate the effects of adding chitosan, silver, and zinc oxide nanoparticles to tissue conditioner materials in patients with denture stomatitis.

Design

Clinical trial with a sample size of 6 patients in 7 parallel groups, without blindness

Settings and conduct

This study will be performed among patients referring to Tabriz Dental School. Patients will be randomly divided into two groups. In the first group, patients will receive conventional tissue conditioners (control group) and in the second to seventh groups, patients will receive tissue conditioners containing silver, zinc oxide and chitosans nanoparticles with a weight percentage of 0.675 and 1.25 and 2.5, and 5 and 10 And 20, respectively. Microbial culture (*Candida albicans*, *Enterococcus faecalis*, *Pseudomonas aeruginosa*, *Streptococcus mutans*) will be done before and after the intervention and will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with denture Stomatitis, Having a healthy denture without leaping and discoloration. Exclusion criteria: Use of anti-fungal drugs, antibiotics and corticosteroids in the past month, Allergy to silver, zinc or other drugs

Intervention groups

In the first group, conventional tissue conditioners (GC Corporation, Japan) were placed under the patient's prosthesis for 72 hours (control group) and in the second to seventh groups, respectively, tissue conditioners containing silver, zinc oxide and chitosan nanoparticles (GC Corporation, Japan) with a weight percent of 0.675 and 1.25, and 2.5, and 5, and 10 and 20 for 72 hours under the patient's prosthesis.

Main outcome variables

Colony count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150628022951N9**

Registration date: **2019-05-18, 1398/02/28**

Registration timing: **retrospective**

Last update: **2019-05-18, 1398/02/28**

Update count: **0**

Registration date

2019-05-18, 1398/02/28

Registrant information

Name

milad Ghanizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 5921

Email address

milad.ghanizadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-12, 1397/07/20

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Evaluation of antibacterial and antifungal properties of complete denture tissue conditioners with adding chitosan, silver and zinc oxide nanoparticles

Public title
Antimicrobial effects of nanoparticles in complete prostheses

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with denture Stomatitis Having a healthy denture without leaping and discoloration

Exclusion criteria:

Use of anti-fungal drugs, antibiotics and corticosteroids in the past month Allergy to silver, zinc or other drugs

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2018-08-27, 1397/06/05

Ethics committee reference number

IR.TBZMED.REC.1397.474

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

Colony count

Timepoint

Pre-intervention, 72 hours after intervention

Method of measurement

Measurement of Microorganisms Growth Based on Turbidity with 600 nm Spectrophotometer

Secondary outcomes

empty

Intervention groups

1

Description

Control Group: Receiving common tissue conditioners (GC Corporation, Japan) under prosthesis for 72 hours

Category

Treatment - Drugs

2

Description

First intervention group: Receiving tissue conditioners containing silver, zinc oxide and chitosans nanoparticles (GC Corporation, Japan) with a weight percentage of 0.657 under prosthesis for 72 hours

Category

Treatment - Drugs

3

Description

Second intervention group: Receiving tissue conditioners containing silver, zinc oxide and chitosans nanoparticles (GC Corporation, Japan) with a weight percentage of 1.25 under prosthesis for 72 hours

Category

4**Description**

Third intervention group: Receiving tissue conditioners containing silver, zinc oxide and chitosans nanoparticles (GC Corporation, Japan) with a weight percentage of 2.5 under prosthesis for 72 hours

Category

Treatment - Drugs

5**Description**

Forth intervention group: Receiving tissue conditioners containing silver, zinc oxide and chitosans nanoparticles (GC Corporation, Japan) with a weight percentage of 5 under prosthesis for 72 hours

Category

Treatment - Drugs

6**Description**

Fifth intervention group: Receiving tissue conditioners containing silver, zinc oxide and chitosans nanoparticles (GC Corporation, Japan) with a weight percentage of 10 under prosthesis for 72 hours

Category

Treatment - Drugs

7**Description**

Sixth intervention group: Receiving tissue conditioners containing silver, zinc oxide and chitosans nanoparticles (GC Corporation, Japan) with a weight percentage of 20 under prosthesis for 72 hours

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz Dental Faculty

Full name of responsible person

Hamed Aghajanzadeh

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Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

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Email**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Abolgasem Joyban

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research-vice@tbzmed.ac.ir

Web page address

<https://researchvice.tbzmed.ac.ir/>

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

No

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Amin Mousavi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic information of patients and data related to the outcomes of the study will be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Sharing data for meta-analysis

From where data/document is obtainable

Please contact Dr.Hamed Aghajanzadeh by e-mail: hhaghajanzadeh@gmail.com

What processes are involved for a request to access data/document

After ensuring that your claim is true, these data will be sent to you.

Comments