

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 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 chitosan 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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Hamed Aghajanzadeh  
**Position**  
Student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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## Person responsible for updating data

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**Position**  
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**Latest degree**  
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**Other areas of specialty/work**

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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