

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Studying antibacterial and anti fungal properties by adding chitosan to complete denture tissue conditioners

Protocol summary

Study aim

Studying antibacterial and antifungal properties by adding chitosan to complete denture tissue conditioners

Design

Individuals who need to be treated with tissue conditioners, randomly divided into seven groups. In the first group, patients receive the common tissue conditioners (control group) and in the second to seventh groups, patients have used tissue conditioners of Chitosan nanoparticles with a weight percent of 0.675, 1.25, 2.5 and 5, 10, and 20, respectively. Before the intervention and after 72 hours, the microbial culture is introduced from the mouth and into the denture samples by sterilized swabs for determined the rate of growth, proliferation, and activity of 4 microorganisms (Enterococcus faecalis, Pseudomonas aeruginosa, Streptococcus mutans and Candida albicans).

Settings and conduct

Seven groups participated in the study. The first group patients received the common tissue conditioners (control) and other 6 groups received a variety weight of Chitosan nanoparticles. None of the patients didn't inform about another Patient's materials. The person doing was also not aware of the type of material. Before the intervention and after 72 hours, the microbial culture is introduced from the mouth and into the denture samples by sterilized swabs for determined the rate of growth, proliferation, and activity of microorganisms.

Participants/Inclusion and exclusion criteria

Entrance criteria: Complete satisfaction to participate in the study-Patients with denture stomatitis Exit criteria: Drug and cigarette consumption-Sensitivity to the tested material

Intervention groups

The first group patients received the common tissue conditioners (control) and other 6 groups received Chitosan nanoparticles with a weight of 0.675, 1.25, 2.5 and 5, 10, and 20 respectively.

Main outcome variables

The amount of colonies produced by the use of Chitosan nanoparticles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181130041801N1**

Registration date: **2019-04-25, 1398/02/05**

Registration timing: **retrospective**

Last update: **2019-04-25, 1398/02/05**

Update count: **0**

Registration date

2019-04-25, 1398/02/05

Registrant information

Name

Amin Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 5965

Email address

mousavigazikandi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2019-03-06, 1397/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying antibacterial and anti fungal properties by adding chitosan to complete denture tissue conditioners

Public title

Studying antibacterial and anti fungal properties by adding chitosan to complete denture tissue conditioners

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Complete satisfaction to participate in the study Patients with denture stomatitis

Exclusion criteria:

Drug and cigarette consumption Sensitivity to the tested material

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 42

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method was randomized among individuals referring to the dental prosthodontics department of Tabriz Dental faculty. The randomization method is simple and the unit is the individual. Our tool to randomization is the randomized Number Chart. In this way, 42 people selected for study with numerical numbers were divided into seven groups. Common tissue Composer and materials with different weight percentages of Chitosan identified with codes A to G and sealed in envelopes that were placed in a Box and stirred.; Then they are randomly chosen from the Box and after observing the code, each material code was assigned to groups 1 to 7, respectively. None of the patients didn't inform about another Patient's materials. The person doing was also not aware of the type of material.

Blinding (investigator's opinion)

Double blinded

Blinding description

The current study is Double-blinded. Participants are unaware of the existence of several types of tissue conditioners in the study and are not aware of other participants. The person evaluating the growth of the bacterias is not aware of the type of group that provides a sample from it.

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

Floor3, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2019-02-04, 1397/11/15

Ethics committee reference number

IR.TBZMED.REC.1397.911

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 of the studied microbes

Timepoint

Before and 72 hours after intervention

Method of measurement

Colony count Cfu- Spectrometry

Secondary outcomes

empty

Intervention groups**1****Description**

Control group: The patients received the common tissue conditioners

Category

Treatment - Drugs

2**Description**

Intervention group1: The patients received the chitosan tissue conditioners with a 0.675 weight percentage

Category

Treatment - Drugs

3**Description**

Intervention group2: The patients received the chitosan tissue conditioners with a 1.25 weight percentage

Category

Treatment - Drugs

4**Description**

Intervention group3: The patients received the chitosan tissue conditioners with a 2.5 weight percentage

Category

Treatment - Drugs

5**Description**

Intervention group4: The patients received the chitosan tissue conditioners with a 5 weight percentage

Category

Treatment - Drugs

6**Description**

Intervention group5: The patients received the chitosan tissue conditioners with a 10 weight percentage

Category

Treatment - Drugs

7**Description**

Intervention group6: The patients received the chitosan tissue conditioners with a 20 weight percentage

Category

Treatment - Drugs

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

Tabriz University of Medical Sciences Dentistry
Faculty dental prosthesis Department

Full name of responsible person

Seyyed Amin Mousavi Ghazikandi

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

Tabriz University of Medical Sciences

Full name of responsible person

Prof. Abolghasem Jouyban

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

Yes

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

Seyyed Amin Mousavi Ghazikandi

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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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available