Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 microbs
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 a1.25 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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Floor3, central building No.2, Tabriz University of Medical Sciences, Golgasht St.
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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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Floor3, Central Building No.2, Tabriz University of Medical Sciences, Golgasht St.
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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
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Person responsible for updating data

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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