

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of Propolis Mouthwash and Placebo Effect on Denture Stomatitis Treatment in Denture Wearers -A Clinical Trial Study.

Protocol summary

Study aim

Determining the effect of Propolis mouthwash on denture stomatitis treatment

Design

This study is a randomized, double blind, parallel group clinical trial with control group.

Settings and conduct

This study is performed on sixty 40-80-year-old patients among persons referred to the Semnan dental school who have lesions due to denture stomatitis. The patients are randomly divided into two groups of thirty patients in each group. In case and control group, the Propolis and Placebo mouthwash, are given respectively, to gargle a dose three times in a day, 3-5 minutes in each turn, and continue until ten days. Accordingly, the patient and the person who performs the clinical examination are not aware of the type of mouthwash. Then, on the first, fifth and tenth day after the beginning of the study, samples are examined for the severity of the lesions through clinical examination.

Participants/Inclusion and exclusion criteria

80-40 year old patients who are attended Semnan dental school and have denture stomatitis.

Intervention groups

Sixty patients are randomly divided into two case and control groups. In the case group, Propolis mouthwash (Mashhad Soren Tak Toos, with 30% extraction) and for control group distilled water plus authorized additives as Placebo (from Co. as mentioned earlier) with similar characteristics in color, odor, condition and bottles are given to the patients.

Main outcome variables

Treatment of fungal lesions caused by denture stomatitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170828035942N2**

Registration date: **2018-03-05, 1396/12/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-05, 1396/12/14**

Update count: **0**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

maryam jalili sadrabad

Name of organization / entity

semnan university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 23 3333 4657

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Semnan University of Medical Sciences.

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Propolis Mouthwash and Placebo Effect on Denture Stomatitis Treatment in Denture Wearers -A

Clinical Trial Study.

Public title
Propolis Effect on Denture Stomatitis Treatment.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
40-80 years old Patients with Denture Stomatitis lesions
Exclusion criteria:

Age
From **40 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Sixty patients are randomly divided into two groups in the present research, consist of thirty case and control people. The randomizing process is done by using the random numbered bottles, according to a random numbers table. Therefore, the patient and the person who performs the clinical examination doesn't know the type of mouthwash.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, the patient, the person who gives the drug to the patient, the investigators and administrators, the person who examines the patient about the effect of the drug, the person who performs the statistical analysis, and observer are not aware of type of drugs (Propolis or placebo).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Semnan University of Medical Sciences

Street address
Vice chancellor for research, Setad Building, Basij blvd

City
Semnan

Province
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Postal code
35198-99951

Approval date
2017-07-12, 1396/04/21

Ethics committee reference number
IR.SEMUMS.REC.1396.57

2

Ethics committee
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Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
ir.semums.rec.1396.57

Health conditions studied

1

Description of health condition studied
denture stomatitis

ICD-10 code
B37.0

ICD-10 code description
candidal stomatitis

Primary outcomes

1

Description
Clinical improvement of infection

Timepoint
day 1, 5 and 10 after intervention

Method of measurement
clinical scoring

Secondary outcomes

1

Description
no need

Timepoint

no need
Method of measurement
no need

Intervention groups

1

Description

Intervention group: Propolis mouthwash with 30% extraction, which is produced by Mashhad Tak Toos Soren Co. is employed in this investigation. An instructor firstly explained for the patients how to use the drug; that is, a dose of it must be gargled 3-5 minutes in each turn, three times a day and continue until 10 days. Then, on the first, fifth and tenth days after beginning the study, the samples are examined for the severity of the lesions in the mouth and information is recorded.

Category

Treatment - Drugs

2

Description

To fulfill the objectives of this research, a Placebo mouthwash is utilized which is prepared from the company mentioned above (distilled water and admixtures), with similar characteristics in color, odor, condition and bottles. An instructor firstly explained for the patients how to use the drug; that is, a dose of it must be gargled 3-5 minutes in each turn, three times a day and continue until 10 days. Then, on the first, fifth and tenth days after beginning the study, the samples are examined for the severity of the lesions in the mouth and information is recorded.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan Dental School

Full name of responsible person

Maryam Jalili Sadrabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research center of Semnan Dental School

Full name of responsible person

Dr. Nazila Ameli

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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

Research center of Semnan Dental School

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

Semnan University of Medical Sciences

Full name of responsible person

Dr. maryam jalili sadrabad

Position

assistant professor

Latest degree

Specialist

Other areas of specialty/work

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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

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

Data Dictionary

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