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

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Name of organization / entity
semnan university of medical sience

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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**
Proplolis 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
  - Semnan

**Postal code**
- 35198-99951

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

**Ethics committee reference number**
- IR.SEMUMS.REC.1396.57

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**Ethics committee**
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**Postal code**
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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**
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

Recruitment centers

1
Recruitment center
Name of recruitment center
Semnan Dental School
Full name of responsible person
Maryam Jalili Sadrabad
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Faculty of Dentistry, Semnan University of Medical Sciences, Hefdad Shahrivar St., Saadi Square
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Research center of Semnan Dental School
Full name of responsible person
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Research Renter, Semnan dental school, 17 Shahrivar Blvd
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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
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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