Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison of the effects of Propolis extract and Nystatin mouthwash on denture stomatitis

Protocol summary

Study aim
The aim of this study is to compare the effects of propolis extract and nystatin mouthwash in patients with denture stomatitis.

Design
Clinical trial with a sample size of 20 patients in two 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. At first, the size of the intra-oral erythema will be recorded. In the first group, 20 drops of propolis extract will be used every 8 hours and in the second group 20 drops of nystatin mouthwash will be used every 8 hours. Then the dimensions of intra-oral erythema will be recorded and compared 5,10,15,20 days later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Denture Stomatitis erythematous, Having a healthy denture without leaping and discoloration. Exclusion criteria: Use of anti-fungal drugs, antibiotics and corticosteroids in the past month, Allergy to nystatin or propolis extract.

Intervention groups
In the first group, the patients will be received the propolis extract and in the second group, they will be received nystatin mouthwash.

Main outcome variables
Dimensions of Denture Stomatitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150628022951N7**
Registration date: **2018-09-09, 1397/06/18**
Registration timing: **prospective**
Last update: **2018-09-09, 1397/06/18**
Update count: **0**

Registration date
2018-09-09, 1397/06/18

Registrant information

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Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-17, 1397/07/25

Expected recruitment end date
2019-06-15, 1398/03/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of Propolis extract and Nystatin mouthwash on denture stomatitis

Public title
Effect of Propolis extract on denture stomatitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Denture Stomatitis erythematous healthy denture without leaping and discoloration

Exclusion criteria:

Use of anti-fungal drugs, antibiotics and corticosteroids in the past month Allergy to nystatin and propolis extrac

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method will be used. Each person will be assigned a code, and according to the random number table, each person will be placed in a group

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

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Postal code

5166614766

Approval date

2018-08-06, 1397/05/15

Ethics committee reference number

IR.TBZMED.REC.1397.422

Health conditions studied

1

Description of health condition studied

Denture Stomatitis

ICD-10 code

K12

ICD-10 code description

Stomatitis and related lesions

Primary outcomes

1

Description

Dimensions of denture stomatitis

Timepoint

Pre-intervention, 5,10,15,20 days after intervention

Method of measurement

Measuring the length and width of the erythema with a digital ruler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Rinse out 20 drops of propolis extract every 8 hours

Category

Treatment - Drugs

2

Description

Control group: Rinse out 20 drops of nystatin every 8 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Dental Faculty

Full name of responsible person

Sarvin Daneshpanah

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
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
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Person responsible for updating data

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Web page address

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.Hossein Eslami by e-mail: eslamihosein56@yahoo.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