

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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

###### Name

milad Ghanizadeh

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3335 5921

###### Email address

milad.ghanizadeh@gmail.com

##### 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 extract

**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

**City**

Tabriz

**Province**

East Azarbaijan

**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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Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Abolgasem Joyban

**Street address**

Research deputy of Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street, Tabriz

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researchteam.tbzmed@gmail.com

**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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Hossein Eslami

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

#### Contact

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**Position**

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## 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**