

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Comparison of ginger and nystatin mouthwashes on denture stomatitis

#### Protocol summary

##### Summary

Denture stomatitis is a chronic inflammation of mucous membrane supporting the movable prostheses. This inflammation is accompanied with erythema, swelling of mucous membrane, and occasionally with pain and burning. The goal of this double blind clinical trial study is comparison of ginger and nystatin mouthwashes on denture stomatitis, that will carry on 30 patients with erythematous denture stomatitis. Duration of study is 20 days and patients after filling an informed consent form and demographic form, will be randomly assigned to two groups. Group one will be presented ginger mouthwash, produced by Rozhin Company (Tabriz, Iran) and the second group will be presented nystatin mouthwash, produced by Jabir ibn hayyan pharmaceutical company (Tehran, Iran). Since the method is carried out in a double-blind. Ginger and nystatin mouthwash bottles are identical and indistinguishable by the researcher and offering the mouth of the subjects can be done by a doctor other than researcher. Each person must use mouth washes 4 times daily, each time 20 drops For 60 seconds. Patients were requested to wear their dentures after the application of mouthwash and avoid eating for a half hour. The length and width of the erythema will be measured and recorded in the profile of each case, by the examiner during the meetings at days 0, 5, 10, 15, 20 of the study and the data Will be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014011616246N1**

Registration date: **2015-01-17, 1393/10/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-01-17, 1393/10/27

#### Registrant information

##### Name

Hossein Eslami

##### Name of organization / entity

Tabriz University of Medical Sciences, Faculty of Dentistry

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1327 0408

##### Email address

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#### Recruitment status

##### Recruitment complete

#### Funding source

Tabriz University of Medical Sciences

#### Expected recruitment start date

2014-09-23, 1393/07/01

#### Expected recruitment end date

2014-10-22, 1393/07/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of ginger and nystatin mouthwashes on denture stomatitis

#### Public title

Comparison of ginger and nystatin mouthwashes on denture stomatitis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: 1 . Erythematose denture stomatitis patients. 2 . Willingness to participate in the study. 3 . Masticatory muscle health.(on The clinical examination of the masticatory muscles , tenderness and trismus Should

not be seen). 4 . The ability to use mouthwash. 5 . Mental health. 6 . Denture fit(no signs of loose discoloration )  
Exclusion criteria : 1 . A history of using antifungal drugs, antibiotics, and corticosteroid within the previous month. 2 . Allergy to ginger and nystatin mouthwashes. 3 . Alzheimer’s disease. 4 . Unwillingness to participate in the study. 5 . People with neuromuscular diseases who have no ability to oral hygiene. 6 . people with pinpoint and granular denture stomatitis 7 .People who are not qualified to give personal satisfaction (Such as children and people with mental disabilities).

#### Age

From **30 years** old to **100 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double 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 science

##### Street address

Central Building Vice Chancellor for Research-Vice Chancellor for Research and Technology

##### City

tabriz

##### Postal code

#### Approval date

2014-12-29, 1393/10/08

#### Ethics committee reference number

93147

## Health conditions studied

### 1

#### Description of health condition studied

denture stomatitis

#### ICD-10 code

B37.0

#### ICD-10 code description

Candidal stomatitis Oral thrush

## Primary outcomes

### 1

#### Description

The length of erythem

#### Timepoint

On days: 0 ,5 ,10 ,15 ,20 of study

#### Method of measurement

Digital dial caliper, in hundredths of a millimeter

## Secondary outcomes

### 1

#### Description

The width of erythem

#### Timepoint

On days: 0 ,5 ,15 ,20 of study

#### Method of measurement

Digital dial caliper, in hundredths of a millimeter

## Intervention groups

### 1

#### Description

Intervention group: the members of this group (15 people) will be presented ginger mouthwash, produced by Rozhin Company (Tabriz, Iran). Each person must use mouth washes 4 times daily, each time 20 drops For 60 seconds. Patients were requested to wear their dentures after the application of mouthwash and avoid eating for a half hour. Patient Recommended using drug at a certain time.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: the members of this group (15 people) will be presented nystatin mouthwash, produced by Jabir Ibn Hayyan pharmaceutical Company (Tehran, Iran). Each person must use mouth washes 4 times daily, each time 20 drops For 60 seconds. Patients were requested to wear their dentures after the application of mouthwash and avoid eating for a half hour. Patient Recommended using drug at a certain time.

#### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Department of Oral Medicine, Dental School, Tabriz

**Full name of responsible person**

Dr. Hossein Eslami, Assistant Professor

**Street address**

Faculty of Dentistry , Tabriz university of medical science

**City**

tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice-chancellor for research

**Full name of responsible person**

Dr. Saied Rahimi

**Street address**

Tabriz Faculty of Dentistry

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice-chancellor for research

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Tabriz Dental College

**Full name of responsible person**

Dr. Hosein Eslami

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*