# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

06 Nov 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)

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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**

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## Person responsible for scientific inquiries

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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*