

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Comparison Effect of Ginger Mouthwash and Nystatin Suspension in Patients with Denture Stomatitis

#### Protocol summary

##### Study aim

Comparison of the effect of ginger mouthwash and nystatin suspension in the treatment of denture stomatitis

##### Design

The third phase of the clinical trial, two groups of parallel, each group of 25, were double blinded, randomized

##### Settings and conduct

This study is performed on 50 patients at the Faculty of Dentistry, Islamic Azad University, Tehran Branch of Oral and Maxillofacial Disease. After obtaining informed written consent, the patient is asked about the duration of the use of denture, the manner and frequency of cleaning, and whether or not use denture at night. In order to evaluate the patient's objective symptoms, the area of a region is more specific and widespread than erythema. First, it is done by marking it with a pencil and then measured by a calibrated paper in mm<sup>2</sup>. Measures are used in this study is the "Vi-one" ginger mouthwash And the 100000 UI Nystatin suspension that will be poured into the bottles by the pharmacist and the only difference will be in the numbers that will be inserted as code on them. double blind study is done on 50 patients. Each patient is required to use 5 ml of the drug 4 times a day for 5 minutes each time for 2 minutes as a mouthwash and refrain from eating and drinking for 30 minutes. Erythromatic areas on the first day before starting the drug and days 21,14,7 is measured by the researcher after starting the drug.

##### Participants/Inclusion and exclusion criteria

Entry requirements: patients with denture stomatitis.  
Non entry requirements: Diabetes, xerostomia, immune system weakened due to chemotherapy and radiotherapy, use antibiotics and antifungals over the past 4 weeks.

##### Intervention groups

Ginger Mouthwash Group and Nystatin Suspension Group

##### Main outcome variables

Area of erythema

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190506043489N1**

Registration date: **2020-01-06, 1398/10/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-01-06, 1398/10/16**

Update count: **0**

##### Registration date

2020-01-06, 1398/10/16

##### Registrant information

##### Name

Kiarash Farzan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2642 4970

##### Email address

kiarash.farzan@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-22, 1398/03/01

##### Expected recruitment end date

2020-01-21, 1398/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison Effect of Ginger Mouthwash and Nystatin Suspension in Patients with Denture Stomatitis

### Public title

Effect of Ginger Mouthwash in treatment of Denture Stomatitis

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

All Patients referred with Denture Stomatitis

#### Exclusion criteria:

Diabetes Xerostomia Hypoparathyroidism Immune system changes Radiotherapy Chemotherapy Use of antibiotics and antifungals over the past four weeks

### Age

No age limit

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

### Sample size

Target sample size: 50

### Randomization (investigator's opinion)

Randomized

### Randomization description

The mouthwashes are poured into identical bottles, then numbered in random order, and by simple randomization, using the calculator, we obtain random numbers for the patient and give mouthwash to the patient .

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Ginger mouthwash and nystatin suspension are spilled by the pharmacist in one shape, one color and one size bottles, and their only difference is in the number that will be entered as the code. The study is double blind and researcher and patients do not know the medication content of the bottle.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

Ethics Committee of Islamic Azad University of Medical Sciences, Tehran, Iran

#### Street address

No. 9, 9th Neyestan Ave., Pasdaran Blvd.

#### City

Tehran

#### Province

Tehran

#### Postal code

1946853314

### Approval date

2019-04-28, 1398/02/08

### Ethics committee reference number

ir.iau.dental.rec.1398.007

## Health conditions studied

1

### Description of health condition studied

denture stomatitis

### ICD-10 code

K12.1

### ICD-10 code description

Other forms of stomatitis

## Primary outcomes

1

### Description

Area of erythema in denture stomatitis

### Timepoint

Before the intervention and 7,14,21 days after the intervention

### Method of measurement

Calibrated paper (transparent paper graded to 5 mm squares)

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Patients gargle Vi-One Ginger Mouthwash with 25% zingiber extract, for 21 days, every 6 hours, each time use 15 ml for one minute.

### Category

Treatment - Drugs

2

### Description

Control group: Patients gargle Emad 100,000 UI nystatin

suspensions, for 21 days, every 6 hours, each time use 15 ml for one minute.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Faculty of Dentistry Islamic Azad University, Tehran  
Branch Oral and Maxillofacial Diseases Departme

**Full name of responsible person**

Somayeh Alirezaei

**Street address**

No. 9, 9th Neyestan Ave., Pasdaran Blvd.

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**Postal code**

1946853314

**Phone**

+98 21 2256 4571

**Fax**

**Email**

Dr.somayehalirezaei@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Kiarash Farzan

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**Email**

kiarash.farzan@yahoo.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University

**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**

Islamic Azad University

**Full name of responsible person**

Kiarash Farzan

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Somayeh Alirezaei

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Kiarash Farzan

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

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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**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not 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**

At the end of the study, the results are shared with patients' confidentiality.

**When the data will become available and for how long**

The access period begins in 2020 after the results are published as a thesis.

**To whom data/document is available**

Access to data is subject to the confidentiality of patients' personal information, only to researchers at academic centers.

**Under which criteria data/document could be used**

After publishing this study, access to the article is granted and there is no condition for its use.

**From where data/document is obtainable**

Applicants can apply for the document at [www.jrds.ir](http://www.jrds.ir).

**What processes are involved for a request to access data/document**

After being published on [www.jrds.ir](http://www.jrds.ir), the documentary is made available to applicants by searching at this website.

**Comments**