Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 mm2. 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Kiarash Farzan

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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

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Assistant Professor

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Specialist

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Kiarash Farzan

Position
Student

Latest degree
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Dentistry

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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.

What processes are involved for a request to access data/document
After being published on www.jrds.ir, the documentary is made available to applicants by searching at this website.

Comments