Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of V-One mouthwash (ginger); Irsha (ginger and yarrow) and nystatin on the amount of oral mucosal erythema in people with denture stomatitis type 2: a clinical trial

Protocol summary

Study aim
Comparison of the effect of V-One ginger mouthwash; Irsha's ginger and yarrow mouthwash and nystatin in the treatment of denture stomatitis type 2, through a clinical trial, in the Faculty of Dentistry of Tehran Islamic Azad University of Medical Sciences in 2023-2024

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 54 patients. The rand function of Excel software was used for randomization.

Settings and conduct
This double-blind clinical trial study is conducted on all patients with denture stomatitis type II referred to the Department of Oral Diseases / Complete Prosthetics of the Faculty of Dentistry of Islamic Azad University in 2023-2024. None of the participants nor the researcher knows about the type of mouthwash.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with type II erythematous stomatitis dentures; ability to use mouthwash. Exclusion criteria: People who are allergic to ginger, yarrow and nystatin mouthwash; have a diet rich in ginger; suffer from diabetes; hypoparathyroidism; history of chemotherapy and radiotherapy; use of antibiotics and anti-fungals in the last 4 weeks

Intervention groups
Intervention Group 1: using V One mouthwash; Intervention Group 2: using Irsha mouthwash; Control Group: using Nystatin suspension

Main outcome variables
Area of erythema in mucosa

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231021059788N1**
Registration date: **2024-01-16, 1402/10/26**
Registration timing: **prospective**

Last update: **2024-01-16, 1402/10/26**
Update count: **0**

Registration date
2024-01-16, 1402/10/26

Registrant information

Name
Sayyed Mohammad Zamaan Mousavi Kaani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-20, 1402/10/30

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of V-One mouthwash (ginger); Irsha (ginger and yarrow) and nystatin on the amount of oral mucosal

erythema in people with denture stomatitis type 2: a clinical trial

Public title
Comparison of the effect of V-One mouthwash (ginger) and Irsha mouthwash (ginger and yarrow) and nystatin in the treatment of denture osteomatitis type 2

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The presence of symptoms of oral candidiasis in the patient's palate Being literate in reading and writing Being able to use mouthwash

Exclusion criteria:
Individuals who are allergic to ginger, yarrow and/or nystatin mouthwash Individuals who have a diet rich in ginger having diabetes Having hypoparathyroidism History of chemotherapy and radiotherapy Use of antibiotics and antifungals during the last 4 weeks

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Bottles that are completely similar in appearance to each other, are poured by one of the three drugs that is going to be examined in the study. For each drug there will be 18 bottles and each bottle suffices for use of a patient during one week and after one week it must be refilled. The bottles are numbered randomly from 1 to 54 and the characteristics of bottles are recorded in the database. A simple randomization method will be used. During the delivery of the medicine to the patient, random number generation software (Microsoft Excel 2013) will be used to assign a random number from 1 to 54 to each patient, and the person receives a bottle containing medicine with the corresponding number. Because it takes time to find related people to enter the study and their visit to the clinic for initial examination and required documentation and signing informed consent is done on different days, therefore, the people participating in the study do not have any contact with each other and hence allocation concealment is implemented in practice.

Blinding (investigator's opinion)
Double blinded

Blinding description
Bottles containing mouthwash are already filled and numbered by the supervisor. The specifications of the mouthwash are recorded and kept by him in the sheet. The bottles containing the mouthwashes are completely similar in appearance and the contents of the bottles are not visible from the outside

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Faculty of Dentistry, Tehran Islamic Azad University of Medical Sciences

Street address
No. 4; Nistan Dahom; Pasdaran street

City
Tehran

Province
Tehran

Postal code
19585/175

Approval date
2023-10-14, 1402/07/22

Ethics committee reference number
IR.IAU.DENTAL.REC.1402.094

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
The area of erythema in the mucosa

Timepoint
Measurement of mucosal erythema area at the beginning of the study (before the intervention) and 7, 14 and 21 days after the start of mouthwash use.

Method of measurement
Area measurement module in ImageJ image processing software

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: use of Irsha's ginger and yarrow mouthwash. The concentration of effective ingredients is 25%. Five ml of mouthwash is swirled in the mouth 4 times a day for 3 minutes each time and then thrown away. Produced by Shafa Pharmaceutical Laboratory - Tehran - Iran

Category
Treatment - Drugs

2

Description
Intervention group 2: use of ginger mouthwash V One. The concentration of effective ingredients is 25%. 5 ml of mouthwash is swirled in the mouth 4 times a day for 3 minutes each time and then thrown away. Produced by Rojin company. Tehran Iran

Category
Treatment - Drugs

3

Description
Intervention group: Use of nystatin suspension. 100000 units. 5 ml of mouthwash is swirled in the mouth 4 times a day for 3 minutes each time and then thrown away. Produced by Jaber Bin Hayan Company - Tehran - Iran

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of Dentistry, Azad University of Tehran

Full name of responsible person
Dr Arezoo Alaei

Street address
No. 4; Nistan Dahom; Pasdaran street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
by myself

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Seyed Mohammad Zamaan Mousavi Kaani

Position
student

Latest degree
Master

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available