

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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)

Phone

+98 21 5554 6976

Email address

m.mousavik@gmail.com

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		similar in appearance and the contents of the bottles are not visible from the outside	
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	Placebo	Not used
Purpose	Treatment	Assignment	Parallel
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	Other design features	
Age	From 18 years old	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	3	1	
Groups that have been masked	- Participant - Investigator	Ethics committee	
Sample size	Target sample size: 54	Name of ethics committee	Ethics Committee of Faculty of Dentistry, Tehran Islamic Azad University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	No. 4; Nistan Dahom; Pasdaran street
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.	City	Tehran
Blinding (investigator's opinion)	Double blinded	Province	Tehran
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	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

City

Tehran

Province

Tehran

Postal code

19585/175

Phone

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Email

m.mousavik@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arezoo alaei

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Province

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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