Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The Antifungal Effect of Punica granatum Mouthwash on Oral Candidiasis: a clinical trial

Protocol summary

Study aim
Evaluation of the lesion size and candida colony count before and after using Punica granatum mouthwash and treatment with nystatin and comparing them

Design
This is a parallel, double blind randomized clinical trial (phase 2) with control group on twenty four patients in each group who will be enrolled randomly by block randomization.

Settings and conduct
Participants with denture stomatitis attending the Shiraz University of Dental School will be enrolled in this study. In the intervention group, nystatin therapy and Punica granatum mouthwash will be considered 3 times a day for 15 days. In the control group, just nystatin therapy will be prescribed. Their effect will be compared. The data analyzer and also the outcome assessor will not know the type of treatment, and both will be blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria : patient with denture stomatitis exclusion criteria: diabetic patient, patient who used antibiotic or anti fungal or corticosteroids within last 3 months, immune suppressed patients.

Intervention groups
Intervention group: Patients with denture stomatitis will be treated by nystatin solution (Jaber-ebn-Haian company, Tehran, Iran). In addition, Punica granatum mouthwash will be prescribed for patients three times a day for 15 days. Control group: Patients with denture stomatitis will be treated with nystatin solution three times a day for 15 days.

Main outcome variables
lesion size, colony count

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120101008585N14**
Registration date: **2022-03-28, 1401/01/08**
Registration timing: **prospective**

Last update: **2022-03-28, 1401/01/08**
Update count: **0**

Registration date
2022-03-28, 1401/01/08

Registrant information

Name
Fatemeh Lavaee

Name of organization / entity
Shiraz Dental School

Country
Iran (Islamic Republic of)

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+98 71 1631 9309

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lavaeef@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2023-03-11, 1401/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Antifungal Effect of Punica granatum Mouthwash on Oral Candidiasis: a clinical trial

Public title

Antifungal Effect of Punica granatum Mouthwash on Oral Candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Edentulous denture-wearing patients with denture stomatitis

Exclusion criteria:

Immunosuppressive patient Diabetic patient The patient who used antibiotic, antifungal medication, or corticosteroid during the last 3 months patients under Chemotherapy or radiotherapy

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Each block with 4 allocations, consisting 2 allocation for intervention and 2 for control group will be considered. Six possible sequence of treatment allocation in each block will be listed and each one will be written on a card. Each time a block will be selected and the sequence of treatment will be registered until the treatment allocations become completed for all 48 participants (12 blocks). The randomization was performed by a methodologist. Allocation concealment will be done by the main researcher. On each 48 cards a sequence will be written and sealed. Pockets will be put in a box. A pocket will be allocated for each participant based on order of enrollment.

Blinding (investigator's opinion)

Double blinded

Blinding description

The outcome assessor and statistical analyzer will be blind to the prescribed treatment. Nystatin oral suspension will be prescribed in both groups. In the intervention group, Punica granatum mouthwash will be added. Since the outcome analyzer will be different from the one who prescribed the mouthwashes, the outcome assessor will be blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Namazi square, Zand street, Shiraz, Iran

City

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Province

Fars

Postal code

7186781559

Approval date

2019-07-07, 1398/04/16

Ethics committee reference number

IR.SUMS.DENTAL.REC.1398.074

Health conditions studied

1

Description of health condition studied

Denture stomatitis

ICD-10 code

B37.0

ICD-10 code description

Candidal stomatitis

Primary outcomes

1

Description

Lesion size

Timepoint

Day 1 and 15 and 30

Method of measurement

Newton's classification

2

Description

candida colony count

Timepoint

Day 1 and 15 and 30

Method of measurement

CFU/ml colony count

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Nystatin oral suspension (100 000 U manufactured by Jaber-ebn-Haian) will be prescribed to swish it for 4 min, gargle, and then expectorate it three times daily for 15 days. In addition, Punica granatum mouthwash will be prescribed 3 times a day for 15 days.

Category

Treatment - Drugs

2

Description

Control group: Nystatin oral suspension (100 000 U manufactured by Jaber-ebn-Haian company) will be prescribed to swish it for 4 min, gargle, and then expectorate it three times daily for 15 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Shiraz University of Medical Sciences

Full name of responsible person

Fateme Lavaee

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Shiraz Dental School, Ghasrdasht street, Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab Memarpour

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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

Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Lavaee

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Position

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is 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
All collected data will be shared after deidentification of participants.

When the data will become available and for how long
6 months after publication data will become available.

To whom data/document is available
The researchers in academic institutions.

Under which criteria data/document could be used
The researchers in academic institutions.

From where data/document is obtainable
The researchers in academic institutions can email responsible person and request information.

What processes are involved for a request to access data/document
The researchers in academic institutions can email responsible person and request information.

Comments