Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison of the effects of Grape seed extract and Nystatin mouthwash on denture stomatitis

Protocol summary

Study aim
The aim of this study is to compare the effects of grape seed extract and nystatin mouthwash in patients with denture stomatitis.

Design
Clinical trial with a sample size of 20 patients in two parallel groups, without blinding

Settings and conduct
This study will be performed among patients referring to Tabriz Dental School. Patients will be randomly divided into two groups. At first, the size of the intra-oral erythema will be recorded. In the first group, 20 drops of grape seed extract will be used every 8 hours and in the second group 20 drops of nystatin mouthwash will be used every 8 hours. Then the dimensions of intra-oral erythema will be recorded and compared 5,10,15, 20 days later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: suffering denture stomatitis erythematous; having a healthy denture without leaping and discoloration. Exclusion criteria: use of anti-fungal drugs, antibiotics and corticosteroids in the past month; allergy to nystatin or grape seed extract.

Intervention groups
In the first group, the patients will be received the grape seed extract and in the second group, they will be received nystatin mouthwash.

Main outcome variables
Dimensions of Denture Stomatitis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150628022951N6**
Registration date: **2018-09-05, 1397/06/14**
Registration timing: **prospective**
Last update: **2018-09-05, 1397/06/14**
Update count: **0**

Registration date
2018-09-05, 1397/06/14

Registrant information

Name
milad Ghanizadeh

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 41 3335 5921

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milad.ghanizadeh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-12, 1397/07/20

Expected recruitment end date
2019-06-20, 1398/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of Grape seed extract and Nystatin mouthwash on denture stomatitis

Public title
Effect of grape seed extract on denture stomatitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering denture stomatitis erythematous Having a healthy denture without leaping and discoloration

Exclusion criteria:

Use of anti-fungal drugs, antibiotics and corticosteroids in the past month Allergy to nystatin and grape seed extract

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method will be used. Each person will be assigned a code, and according to the random number table, each person will be placed in a group

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street,Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2016-08-05, 1395/05/15

Ethics committee reference number

IR.TBZMED.REC.1397.423

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

Dimensions of denture stomatitis

Timepoint

Pre-intervention, 5,10,15, 20 days after intervention

Method of measurement

Measuring the length and width of the erythema with a digital ruler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Rinse out 20 drops of grape seed extract every 8 hours

Category

Treatment - Drugs

2

Description

Control group: Rinse out 20 drops of nystatin every 8 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Dental Faculty

Full name of responsible person

Sanam Khanmoradi

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Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street,Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolgasem Joyban

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Research deputy of Tabriz University of Medical Sciences, Golgasht Avenue, Azadi Street,Tabriz

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researchteam.tbzmed@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hossein Eslami

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Web page address

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
Demographic information of patients and data related to the outcomes of the study will be shared.
When the data will become available and for how long
The access period starts 6 months after the results are published.
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Sharing data for meta-analysis
From where data/document is obtainable
Please contact Dr.Hossein Eslami by e-mail: eslamihosein56@yahoo.com
What processes are involved for a request to access data/document
After ensuring that your claim is true, these data will be sent to you.
Comments