

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A clinical trial of comparison of ginger mouthwash and nystatin suspension on treatment of denture osteomatitis among denture patients

Protocol summary

Summary

The purpose of current study is to evaluate the effects of ginger mouthwash on treatment of denture stomatitis (DS). This is a randomized double-blind clinical trial and 25 patients were included in each group. The subjects were randomly assigned to receive ginger mouthwash (group I) or nystatin mouthwash (group II). Two groups were similar regarding the grade of DS. Group I were instructed to rinse their mouth with 5 ml of ginger mouthwash 2%, while group II used 100000 of nystatin mouthwash. Both groups used mouthwash 3 times a day for 15 days. The patients were advised to swish mouthwash for 3 minute and avoid eating and drinking for 30 minutes afterwards. Ginger and nystatin mouthwash bottles were in an identical shape and the patients or the researcher evaluating the outcomes were unaware of the drug inside the bottles. Inclusion criteria: denture stomatitis. Exclusion criteria: history of taking corticosteroids, antibiotics, antifungals or immunosuppressive during last month, having immunosuppression illness, history of allergic reaction to ginger or nystatin, Alzheimer's disease or masticatory muscles disorder. Assessment of erythematous lesions was performed at the end of first and second week. A fungul culture was prepared from palate at the end of first session and also at final session. The patients' satisfaction degree of using either ginger or nystatin mouthwashes were documented as very good, good, relatively good, poor and very poor.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016060818479N2**

Registration date: **2016-07-17, 1395/04/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-17, 1395/04/27

Registrant information

Name

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Name of organization / entity

Babol University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Babol University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-05-04, 1395/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial of comparison of ginger mouthwash and nystatin suspension on treatment of denture osteomatitis among denture patients

Public title

Efficacy of ginger mouthwash on treatment of denture stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: who has denture osteomyelitis.

Exclusion criteria: history of taking corticosteroids, antibiotics, antifungals or immunosuppressive drugs during last month; having immunosuppressive illness; history of allergic reaction to ginger or nystatin; Alzheimer disease or masticatory muscles disorders

Age

From 25 years old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients were allocated to intervention and control groups using random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Ganjafroz Street, Daneshgah Square, Babol University of Medical Sciences

City

Babol

Postal code

4717641367

Approval date

2016-05-01, 1395/02/12

Ethics committee reference number

MUBABOL.REC.1395.7

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

Treatment duration

Timepoint

end of first and second week

Method of measurement

clinical change in erythematose zone

Secondary outcomes

1

Description

Number of colonies

Timepoint

First visit, end of second week

Method of measurement

culture preparing

Intervention groups

1

Description

Intervention group: ginger mouthwash 2%, 5 ml ,3 times a day, for 2 weeks

Category

Treatment - Drugs

2

Description

control group: nystatin mouthwash 100000 u/ml ,5 ml, 3 times a day, for 2 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral medicine department, Babol School of Dentistry

Full name of responsible person

Zahra Allizadeh

Street address

Dental School, Babol University of Medical Sciences, Ganjafroz Street, Daneshgah Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Babol University of Medical Sciences

Full name of responsible person

Dr Aliakbar Moghadamnia

Street address

Ganjafrooz Street, Daneshgah Square, Babol University of Medical Sciences

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Zahra Alizadeh

Position

Post graduate student

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty