Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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

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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 osteomatitis. 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
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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
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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
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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
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
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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