Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation the effect of 0.5% chitosan mouth wash on recurrent aphthous stomatitis. (Double blind Crossover Randomized Clinical Trial)

Protocol summary

Summary

The purpose this study is to evaluate the effects of 0.5% chitosan mouthwash on recurrent aphthous stomatitis .This is a randomized ,double - blind ,crossover clinical trial. Inclusion criteria:People with a history of minor oral aphthous lesions in the mucosa of the cheek or lip,at least fourPeriods per year ؛ The age group 18 to 50 years. Exclusion criteria:minor or multiple minor aphthous ulcers ؛ ulcers in other sites expect labial and buccal mucosa ؛ present of any systemic diseases that developed oral ulcers ؛ bechet disease؛ hematologic diseases ؛ taking chemotherapic drugs؛ pregnant and nursing weman.20 patients with recurrent aphthous stomatitis history are selected from the students of Babol university of medical sciences and patients referred to oral medicine department ,school of dentistry, Babol university of medical sciences. Each patient is monitored in four periods of aphthous ulcers and one period without treatment and just monitoring the ulce and three periods with taking one of biogel, triamcinolone or chitosan mouthwash randomly .All patients are visited in 1st, 3rd, 5th, 7th and 10th days at each period.Primary outcomes include:Pain intensity(VAS) and ulcer size(mm2).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030718753N2**
Registration date: **2016-02-10, 1394/11/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-10, 1394/11/21

Registrant information

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Mina Motallebnejad
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2015-06-01, 1394/03/11

Expected recruitment end date

2016-03-15, 1394/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of 0.5% chitosan mouth wash on recurrent aphthous stomatitis. (Double blind Crossover Randomized Clinical Trial)

Public title

Evaluation the effect of 0.5% chitosan mouth wash on recurrent aphthous stomatitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:People with a history of minor oral aphthous lesions in the mucosa of the cheek or lip,at least four courses per year ؛ The age group 18 to 50 years . Exclusion criteria:minor or multiple minor

aphthous ulcers ؛ulcers in other sites expect labial and buccal mucosa ؛present of any systemic diseases that develope oral ulcers such as gastrointestinal disorders (crohn disease,ulcerative colitis)؛bechet disease؛Reiter syndrome؛hematologic diseases؛malnutrition؛alergic condition ؛consumption of chemotrapic drugs ؛immunosupressive or systemic corticosteroids at past year؛patients with any other mucosal lesions ؛pregnant and nursing weman

Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Babol University of Medical Sciences
Street address
University of Medical Sciences, Ganjafroz Street, Babol
City
Babol
Postal code
4717641367
Approval date
2015-02-03, 1393/11/14
Ethics committee reference number
5121 30/پ/ژ

Health conditions studied

1

Description of health condition studied
Recurrent aphthous stomatitis
ICD-10 code
k12.0
ICD-10 code description
Recurrent oral aphthae

Primary outcomes

1

Description
ulcer size
Timepoint
1st, 3rd, 5th, 7th and 10th days
Method of measurement
gauge measurement

2

Description
pain intensity
Timepoint
firth, third,fifth,seventh and tenth days
Method of measurement
visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
chitosan 0.5% mouth wash 3 times a day until recovery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Oral medicine department, Babol school of dentistry
Full name of responsible person
Fatemeh Rahmani
Street address
University of Medical Sciences, Ganjafroz Street, Babol
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Ali Akbar Moghadamnia
Street address

Babol University of Medical Sciences, Deputy of research & technology

City
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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
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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Post graduate student

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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