

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 chemotherapeutic 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

Name

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Name of organization / entity

Babol University of Medical Sciences

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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 except labial and buccal mucosa :present of any systemic diseases that develop oral ulcers such as gastrointestinal disorders (crohn disease,ulcerative colitis):bechet disease:Reiter syndrome:hematologic diseases:malnutrition:allergic condition :consumption of chemotherapeutic drugs :immunosuppressive or systemic corticosteroids at past year:patients with any other mucosal lesions :pregnant and nursing woman

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

first, 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

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University of Medical Sciences, Ganjafroz Street,
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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

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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

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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