

# 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

Mina Motallebnejad

##### Name of organization / entity

Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 911 111 4191

##### Email address

m.motallebnejad@mubabol.ac.ir

##### 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

##### Street address

University of Medical Sciences, Ganjafroz Street,  
Babol

##### City

Babol

## 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**

Babol

**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**

Babol University of Medical Sciences

**Full name of responsible person**

Fatemeh Rahmani

**Position**

Post graduate student

**Other areas of specialty/work**

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**Full name of responsible person**

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**Position**

full profesor

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**Web page address**

**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*