

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of Aloe vera mouthwash and Placebo on postoperative complications in patients with bilateral impacted mandibular third molar teeth

#### Protocol summary

##### Summary

A randomized double-blind clinical trial study to comparison of Aloe vera mouthwash and Placebo on postoperative complications after third molar surgery will do. The inclusion criteria for this study included: bilateral symmetrically impacted partially erupted mandibular third molar teeth. Patients will exclude from the study if they had a history of systemic disease; drug abuse; smoking and pregnant or lactating patients. 25 patients undergoing surgical removal of bilateral and symmetrically placed impacted lower third molars will enroll in the study. The minimum interval between the first and the second surgeries will be 2 weeks. 100% pure Aloe Vera Mouthwash with a similar color and taste of normal saline as placebo, is produced (Barij Essence Company, Iran) and The patients will ask to rinse the mouth with 15 ml of mouthwash for 30 seconds, 4 times a day. A single examiner performing all clinical measurements (swelling, pain, trismus, and alveolar osteitis) prior to surgery and 1, 3, 5 and 7 days postoperatively. To evaluate the swelling, distance between the angle of the mandible and the following facial regions is obtain: the tragus, the labial commissure, the nasal border, laterally to the external corner of the eye, and on the soft pogonion. Pain will evaluate using a 10 cm visual analogue scale (VAS). Trismus is evaluating by measuring the distance between the incisal edges of the upper and lower central incisors. The presence of alveolar osteitis (Dry socket) will assess clinically using criteria set out by Blum.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013110515300N1**  
Registration date: **2013-12-07, 1392/09/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-12-07, 1392/09/16

##### Registrant information

###### Name

Atefeh Mohseni nezhad

###### Name of organization / entity

Qazvin University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 1335 3061

###### Email address

amohseninezhad@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Center of Qazvin University of Medical Sciences

##### Expected recruitment start date

2013-11-27, 1392/09/06

##### Expected recruitment end date

2014-02-25, 1392/12/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Aloe vera mouthwash and Placebo on postoperative complications in patients with bilateral impacted mandibular third molar teeth

**Public title**

Effect of Aloe vera mouthwash on complications after third molar surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: bilateral symmetrically impacted partially erupted mandibular third molar teeth; physically health Exclusion criteria: history of systemic disease ; drug abuse; smoking ; pregnancy ; lactating patients .

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 25

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Qazvin University of Medical Science

**Street address**

Bahonar blvd, Qazvin, Iran

**City**

Qazvin

**Postal code**

59811-34197

**Approval date**

2013-07-15, 1392/04/24

**Ethics committee reference number**

28/20/7616

**Health conditions studied****1****Description of health condition studied**

Embedded and impacted teeth

**ICD-10 code**

K01

**ICD-10 code description**

Embedded and impacted teeth

**Primary outcomes****1****Description**

Swelling

**Timepoint**

Prior to surgery and 1 , 3 , 5 and 7 days postoperatively

**Method of measurement**

In millimeter. distance between the angle of the mandible and the following facial regions was obtain: thetragus, the labial commissure, the nasal border, laterally to the external corner of the eye, and on the soft pogonion

**2****Description**

Pain

**Timepoint**

Prior to surgery and 1 , 3 , 5 and 7 days postoperatively

**Method of measurement**

In number 0 to 10 by postoperatively using a visual analogue scale

**3****Description**

Trismus

**Timepoint**

Prior to surgery and 1 , 3 , 5 and 7 days postoperatively

**Method of measurement**

In millimeter by measuring the distance between the incisal edges of the upper and lower central incisors

**4****Description**

Alveolar osteitis

**Timepoint**

Prior to surgery and 1 , 3 , 5 and 7 days postoperatively

**Method of measurement**

The presence or absence that will assess clinically using criteria set out by Blum.

**Secondary outcomes**

empty

**Intervention groups****1****Description**

100% pure Aloe Vera Mouthwash The patients will ask to rinse the mouth with 15 ml of mouthwash for 30 seconds, 4 times a day.

**Category**

Treatment - Drugs

## 2

### Description

Normal saline The patients will ask to rinse the mouth with 15 ml of mouthwash for 30 seconds, 4 times a day.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

School of Dentistry of Qazvin University of Medical Science

##### Full name of responsible person

##### Street address

##### City

Qazvin

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Qazvin University of Medical Science

##### Full name of responsible person

Dr jamshid pursamimi

##### Street address

Bahonar blvd, Qazvin

##### City

Qazvin

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Qazvin University of Medical Science

##### 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

Qazvin University of Medical Science

##### Full name of responsible person

Atefeh Mohseni nezhad

##### Position

Dentistry student

#### Other areas of specialty/work

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

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##### Position

Oral and maxillofacial surgery

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## Person responsible for updating data

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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*