

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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Name of organization / entity

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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

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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

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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

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

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Full name of responsible person

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Other areas of specialty/work

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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