Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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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 salline 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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Bahonar blvd, Qazvin
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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

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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