Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effectiveness of pomegranate peel extract mouth rinse & normal saline on complications of third molar surgery in patients having third molars

Protocol summary

Study aim
Determination of effect of pomegranate peel mouth-rinse on complications of impacted mandibular third molar

Design
This study is a clinical trial with control group and parallel design including 46 cases: 23 patients having bilateral mandibular third molars. This study will be done in both sides of patients mouth , one side as intervention group and the other side as control group

Settings and conduct
The method of study will be as following: pomegranate peel extract mouth rinse will be prescribed for one side of mouth, and normal saline will be prescribed for the other side of mouth after surgery.

Participants/Inclusion and exclusion criteria
Healthy individuals in the range of 20-35 years having bilateral impacted third molars of mandible; without any systemic disease; without Temporo-Mandibular Joint (TMJ) disorder; without limitation of mouth opening; non smoker

Intervention groups
One side of mouth, as intervention group, will be rinsed with pomegranate peel extract mouthrinse after the third mandibular molar surgery. Other side of mouth, as control group, will be rinsed with normal saline after the third mandibular molar surgery.

Main outcome variables
swelling ; incidence of dry socket ; pain ; trismus

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180117038415N1**
Registration date: **2018-03-04, 1396/12/13**
Registration timing: **retrospective**
Last update: **2018-03-04, 1396/12/13**
Update count: **0**

Registration date
2018-03-04, 1396/12/13

Registrant information

Name
Ali Mortazavi

Name of organization / entity

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Iran (Islamic Republic of)

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+98 41 3335 5965

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mortazavia@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-01-02, 1395/10/13

Expected recruitment end date
2018-01-03, 1396/10/13

Actual recruitment start date
2017-01-02, 1395/10/13

Actual recruitment end date
2018-01-03, 1396/10/13

Trial completion date
empty

Scientific title
Comparison of the effectiveness of pomegranate peel extract mouth rinse & normal saline on complications of third molar surgery in patients having third molars

Public title
The effect of pomegranate peel mouth-rinse on complications of wisdom tooth surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals in the age range of 20-35 years having bilateral third molars that are similar in classification of impacted teeth informed consent

Exclusion criteria:

Systemic disease TMJ disorder Limitation of mouth opening smoking

Age

From **20 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **23**

More than 1 sample in each individual

Number of samples in each individual: **2**

Bilateral impacted third mandibular molars

Actual sample size reached: **23**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Bilateral impacted third mandibular molars

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Vice chancellor for researchs & technology affairs, central building no 2, Tabriz University of Medical Sciences, Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2018-01-01, 1396/10/11

Ethics committee reference number

IR.TBZMED.REC.1396.921

Health conditions studied

1

Description of health condition studied

Complications of third molar tooth surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Swelling

Timepoint

Pre-operation, day 1 post-operation, day 3 post-operation, day 7 post-operation

Method of measurement

Measuring the tragus - alar , tragus - mandible angle, mandible angle - alar distances with a string

2

Description

Incidence of dry socket

Timepoint

Observation of surgery area in day 3 post operation , day 7 post-operation

Method of measurement

Observing the surgery area and assessing the symptoms

3

Description

Pain

Timepoint

Day 1 post-operation , day 3 post-operation, day 7 post-operation

Method of measurement

Visual analog scale (asking from patient, scoring from 1 to 10)

4

Description

Trismus

Timepoint

Pre-operation , day 1 post-operation , day 3 post-operation , day 7 post-operation

Method of measurement

Measuring the maximum space between central incisors of maxilla and mandible

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: one side of patients mouth will rinse with pomegranate peel extract mouth rinse with concentration of 2.5 grams per liter for 30 seconds, 4 times a day.
Category
Treatment - Drugs

2

Description
Control group: The opposite side of patients' mouth will be rinsed with normal saline 0.9% mouthwash for 30 seconds, 4 times a day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Faculty of Dentistry
Full name of responsible person
Ali Mortazavi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
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Mohammadreza Rashidi
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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
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ali Mortazavi
Position
Assistant professor
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available