Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Iranian Propolis mouthwash on some complications of mandibular impacted third molar surgery

Protocol summary

Study aim

The aim of the present study is to investigate the effect of Iranian propolis mouthwash compared to chlorhexidine mouthwash on the complications (pain, swelling and trismus) after surgery of the impacted third molar of the mandible.

Design

Clinical trial with control group with parallel groups, double-blind, randomized, on 40 patients.

Settings and conduct

Patients referred to the maxillofacial surgeon's office for the surgery of the impacted third molar of the mandible, The surgical conditions are the same for both intervention and control groups. After surgery, the intervention group uses propolis mouthwash and the control group uses 0.2% chlorhexidine mouthwash for one week. On the second and seventh days after the surgery, the amount of swelling, the maximum opening of the mouth, the pain and the number of painkillers consumed are recorded. the surgeon and the patient did not know which mouthwash they used. .

Participants/Inclusion and exclusion criteria

Including healthy people (ASA I or II) Impacted third molar of the mandible (with vertical impact and grade I and A according to the Pell and Gregory criteria) Exclusion criteria include pregnant and lactating people, people under 18 years of age and people who were allergic to honey or used tobacco.

Intervention groups

After the surgical procedure, the intervention group was given a 240 ml bottle containing Iranian propolis mouthwash, and the control group was given a 240 ml bottle containing 0.2% chlorhexidine mouthwash according to the usual procedure of oral surgeries. The patients were taught that for a week. Twice a day after breakfast and before going to bed, swish 15 ml of mouthwash in the mouth for one minute and then take it out of the mouth .

Main outcome variables

The effect of two mouthwashes on pain, swelling and mouth opening rate was similar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230212057392N1**
Registration date: **2024-11-03, 1403/08/13**
Registration timing: **retrospective**

Last update: **2024-11-03, 1403/08/13**
Update count: **0**

Registration date

2024-11-03, 1403/08/13

Registrant information

Name

Faezeh Aghamolaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3216 4121

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-21, 1401/03/31

Expected recruitment end date

2022-09-20, 1401/06/29

Actual recruitment start date

2022-06-21, 1401/03/31

Actual recruitment end date

2022-09-21, 1401/06/30

Trial completion date
2022-10-18, 1401/07/26

Scientific title
Evaluation of the effect of Iranian Propolis mouthwash on some complications of mandibular impacted third molar surgery

Public title
Evaluation of the effect of Iranian Propolis mouthwash on some complications of mandibular impacted third molar surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Healthy people (ASA I or II) The impacted third molar of the mandible (with vertical impact and grades I and A according to the Pell and Gregory criteria People have not taken any type of antibiotics at least two weeks before surgery

Exclusion criteria:
Pregnant and lactating people People under 18 years old People who are allergic to honey Tobacco user

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The people who referred to the personal office of oral, maxillofacial surgery specialist for mandibular impacted third molar surgery were randomly divided into two equal control and intervention groups .Randomization was carried out in such a way that patients were given numbers according to the day and time of their visit to the office, and the numbers were randomly assigned to two intervention and control groups using Excel.

Blinding (investigator's opinion)
Double blinded

Blinding description
The packaging bottles of the two mouthwashes had a completely similar appearance, and the surgeon and the patient did not know which mouthwash they had used.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Rafsanjan University of Medical Sciences

Street address
Central Organization - Imam Ali Boulevard

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Approval date
2022-06-07, 1401/03/17

Ethics committee reference number
IR.RUMS.REC.1401.049

Health conditions studied

1

Description of health condition studied
A patient who needs surgery for an impacted third molar of the mandible (with vertical impaction and grades I and A according to the Pell and Gregory criteria

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
swelling

Timepoint
Before surgery, the second and seventh days after surgery

Method of measurement
The amount of swelling was measured based on the change of facial reference points. The distances between the reference points were measured and recorded using a cloth meter. These distances included the tragus to the midline of the tooth and the angle of the mandible to the midline of the tooth, which was measured with a tape measure.

2

Description
The maximum amount of mouth opening

Timepoint
Before surgery, the second and seventh days after surgery

Method of measurement

The patient was asked to open his mouth straight as far as he could so that he did not have any jaw deviation and did not suffer pain, then the distance between the upper and lower centers was measured with a ruler.

3

Description
Pain
Timepoint
Second and seventh day after surgery
Method of measurement
Visual analog scale control and evaluation method

4

Description
Number of painkillers used
Timepoint
Second and seventh day after surgery
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After the surgical procedure, the intervention group was given Iranian propolis mouthwash. The mouthwash used contained 1% propolis with a salt concentration of 0.25%, which was prepared in the laboratory of the Faculty of Dentistry. The patient was instructed to swish 15 ml of mouthwash in the mouth for one minute for a week, twice a day after breakfast and before bed, and then remove it from the mouth, and to refrain from eating and drinking for 30 minutes.
Category
Treatment - Drugs

2

Description
Control group: For the control group, according to the usual oral surgery procedure, a bottle containing 0.2% chlorhexidine mouthwash (V-One, Tabriz, Iran) was given. The patient was instructed to swish 15 ml of the mouthwash in the mouth for one minute twice a day for one week after breakfast and before going to bed, and then to remove it from the mouth, and to refrain from eating or drinking for 30 minutes. It should be noted that the packaging bottles of the two mouthwashes had a completely similar appearance. surgeon and the patient were unaware of which mouthwash they had used. Also, patients were not allowed to use any other mouthwash during the study period.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Oral and maxillofacial surgery specialist's private office
Full name of responsible person
Dr.Ali peimani mojaver
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
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Building No. 3 - Central Organization - Imam Ali Blvd.
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Email
vcrt@rums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
Ali nabavizade
Position
Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
Only a part of the data, such as the information related to the main result or the like, can be shared
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Respecting the author's rights
From where data/document is obtainable
through the mail address faezeh.aghamolaei1997@gmail.com
What processes are involved for a request to access data/document
A period of one month after the request by postal address
Comments