Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of Propolis and chlorhexidine mouthwashes on some complications of impacted mandibular Third molar extraction surgery

Protocol summary

Study aim
Comparison of the effect of propolis mouthwash and 0.02 chlorhexidine on the complications of mandibular impacted third molar surgery.

Design
Phase 3 clinical trial, with cross-over groups, sample size of 20 people, randomized by throwing dice, double-blind

Settings and conduct
The current study is a split mouth clinical trial study, which will be conducted in order to investigate the effect of propolis mouthwash intervention on complications caused by mandibular impacted third molar surgery. All participants will be explained about the intervention, its goals, possible side effects and effects, participants, service providers and people who will perform the data analysis will be blinded to the type of grouping and receiving the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Above 18 years old Healthy people (ASA I or II) (healthy people, a person who has a mild systemic disease and the disease is under control and has not caused any restrictions to the patient) People who need bilateral mandibular impacted third molar surgery (with impact grade one and A based on the Pelland Gregory standard) Not taking antibiotics for at least 2 weeks Absence of any inflammation and acute infection in the surgical area Absence of pregnancy and breastfeeding Absence of smoking and tobacco addiction Not allergic to honey Exclusion criteria: Lack of cooperation and adherence to protocols Smoking and tobacco use

Intervention groups
Consumption of propolis mouthwash and 0.02 chlorhexidine mouthwash as two intervention groups for one week, twice a day after breakfast and before bed for 30 seconds.

Main outcome variables
Swelling rate; pain level; Mouth opening rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240302061143N1**
Registration date: **2024-03-25, 1403/01/06**
Registration timing: **prospective**

Last update: **2024-03-25, 1403/01/06**
Update count: **0**

Registration date
2024-03-25, 1403/01/06

Registrant information

Name
Hamid Seyfi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-13, 1403/01/25

Expected recruitment end date
2024-07-15, 1403/04/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Propolis and chlorhexidine mouthwashes on some complications of impacted mandibular Third molar extraction surgery

Public title
Comparison of the effect of Propolis and chlorhexidine mouthwashes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Above 18 years old Healthy people (ASA I or II) (healthy people, a person who has a mild systemic disease and the disease is under control and has not caused any restrictions to the patient) People who need bilateral mandibular impacted third molar surgery (with impact grade one and A based on the Pelland Gregory standard) Not taking antibiotics for at least 2 weeks Absence of any inflammation and acute infection in the surgical area Absence of pregnancy and breastfeeding Absence of smoking and tobacco addiction Not allergic to honey

Exclusion criteria:
Lack of cooperation and adherence to protocols Smoking and tobacco use

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
Dental surgery in two impacted molars three weeks apart

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the allocation of participants will be done based on the randomization method and by using dice. After selecting people according to the calculated sample size, numbers 1, 3, and 5 are considered for group A and numbers 2, 4, and 6 for group B

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to make the study blind, 40 similar containers were prepared by the first colleague, and A label and B label will be transferred to the containers, and without the knowledge of the second colleague, the contents of each label will be delivered to him, and after the completion of the first surgical procedure, the patients will be The second colleague is randomly divided into two groups, A and B, and the mouthwash of the same group is delivered to the patient, then after three weeks of the first surgery, the patient comes for the second surgery of the impacted tooth on the opposite side, and this time the second mouthwash, which is different It is given with the first one.

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences

Street address
Zanjan University of Medical Sciences, Dr. Yousef Sobouti Boulevard, Zanjan

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Zanjan

Province
Zanjan

Postal code
4513956184

Approval date
2024-02-20, 1402/12/01

Ethics committee reference number
IR.ZUMS.REC.1402.270

Health conditions studied

1

Description of health condition studied
Complications of impacted mandibular Third molar extraction surgery

ICD-10 code
K01

ICD-10 code description
Embedded and impacted teeth

Primary outcomes

1

Description
Degree of swelling

Timepoint
Before the intervention, 2 and 7 days after the intervention

Method of measurement
Tragus to midline distance and mandible angle to dental midline using a ruler

2

Description
Pain level
Timepoint
Before the intervention, 2 and 7 days after the intervention
Method of measurement
Visual Analogue Scale

3

Description
Mouth opening rate
Timepoint
Before the intervention, 2 and 7 days after the intervention
Method of measurement
The distance between upper and lower central teeth using a ruler

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Chlorhexidine 0.02 mouthwashes,Iran Daru Pharmaceutical Company, for one week, twice a day after breakfast and before going to bed, rinse the mouth for 30 seconds.
Category
Treatment - Drugs

2

Description
Intervention group 2: Propolis mouthwashe, Soren Tech Toos Company, for one week, twice a day after breakfast and before going to bed, rinse the mouth for 30 seconds.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Zanjan University of Medical Sciences
Full name of responsible person
Meysam Bigdelou
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Zanjan University of Medical Sciences, Dr. Yousef Sobouti Boulevard, Zanjan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Samad Nadri
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Azadi Square, the beginning of the Islamic Republic Blvd., Zanjan University of Medical Sciences Headquarters, Zanjan
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Grant name
Thesis grant for Mr. Hamid Seyfi's student
Grant code / Reference number
A-11-1667-6
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Meysam Bigdelou
Position

Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Oral and Maxillofacial Surgery

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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
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
The participants' data, including age, gender, pre- and post-study results, will be disclosed at the conclusion of the study at the discretion of the project manager.

When the data will become available and for how long
Access to the data in question will commence one year after the publication of the results.

To whom data/document is available
Researchers, professors, and students with an official document from a research institute, university, industrial, or pharmaceutical centers.

Under which criteria data/document could be used
The data will be accessible to offer guidance on conducting a study or designing similar studies, and there is also the option to undertake meta-analysis studies in collaboration with the project manager; under no other circumstances is the utilization of the data permitted.

From where data/document is obtainable
Applicants can correspond with Dr. Meysam Bigdelou, as the project manager, to receive data.

What processes are involved for a request to access data/document
Issuing certificates from research, academic, and industrial institutions endorsed by that center to meet data requirements and providing a clear explanation of

their objectives concerning the data and how the data will be utilized.

Comments