Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Studying the effect of herbal mouthwash (propolis) on the reduction of gingival index, plaque index, and prevalence of dry socket in impacted mandibular wisdom teeth compared to chlorhexidine

Protocol summary

Study aim
Studying the effect of herbal mouthwash (propolis) on the reduction of gingival index, plaque index, and prevalence of dry socket in impacted mandibular wisdom teeth compared to chlorhexidine

Design
A phase 3, double-blind, randomized, parallel-group, controlled clinical trial was used on 60 patients for simple randomization.

Settings and conduct
The location of the study is the School of Dentistry. Patients will undergo a complete dental examination upon entering the study, complete a demographic information checklist, and be divided into two groups.

Participants/Inclusion and exclusion criteria
Entry requirements: Having impacted wisdom teeth in the lower jaw - Not using other mouthwashes - Plaque index and gum index Conditions of non-entry: Pregnant people - People with cardiovascular problems - People who use antibiotic drugs for any reason

Intervention groups
Intervention group: Effect of herbal mouthwash (propolis) Control group: Simultaneously uses chlorhexidine mouthwash.

Main outcome variables
The amount of gum index reduction-Prevalence of dry cavity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241211064021N4**
Registration date: **2025-03-21, 1404/01/01**
Registration timing: **prospective**
Last update: **2025-03-21, 1404/01/01**
Update count: **0**

Registration date
2025-03-21, 1404/01/01

Registrant information

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Faeze Noori

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
2025-04-12, 1404/01/23

Expected recruitment end date
2025-09-14, 1404/06/23

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the effect of herbal mouthwash (propolis) on the reduction of gingival index, plaque index, and prevalence of dry socket in impacted mandibular wisdom teeth compared to chlorhexidine

Public title
Comparison of the effects of propolis and chlorhexidine mouthwash on oral health and impacted mandibular

wisdom teeth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having impacted wisdom teeth in the lower jaw Not using other mouthwashes Plaque index and gum index

Exclusion criteria:

Pregnant people People with cardiovascular problems People who use antibiotic medications for any reason

Age

From **15 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method will be used to implement random assignment. In this way, 60 consecutive numbers (from 1 to 60) will be written separately on paper and placed in a container. Then, each participant in the experiment will be asked to randomly select one of these 60 numbers from the container containing the numbers.People who chose numbers 1 to 30 will be assigned to Group A, and people who chose numbers 31 to 60 will be assigned to Group B.

Blinding (investigator's opinion)

Double blinded

Blinding description

Propolis mouthwash and chlorhexidine mouthwash are produced with similar appearance, color, and odor. If possible, additives are used to make both mouthwashes look exactly the same. This is done to prevent the mouthwash from being identified based on appearance. Both mouthwashes are packaged in identical, indistinguishable bottles.In this type of blinding, neither the participants know which mouthwash they are receiving nor do the researchers who perform the clinical assessments (such as measuring gingival and plaque indices). The primary investigator codes the bottles (using numbers). This list is not made available to the researchers or participants until the end of the study.Participants are given coded bottles and told to use the mouthwash according to specific instructions (for example, twice a day after brushing their teeth).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh St

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2024-11-23, 1403/09/03

Ethics committee reference number

IR.UMSHA.REC.1403.622

Health conditions studied

1

Description of health condition studied

Studying the effect of herbal mouthwash (propolis) on the reduction of gingival index, plaque index, and prevalence of dry socket in impacted mandibular wisdom teeth compared to chlorhexidine

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

The amount of gum index reduction

Timepoint

Before intervention: Assessment of the initial condition before starting to use the mouthwash. After intervention: Assessment at specific times after the start of treatment, measured on days 7 and 14.

Method of measurement

They are measured using standard clinical methods, which include examination of the teeth and gums by a trained dentist and researcher. Instruments such as a probe are used to measure the depth of the gingival pocket or visual observation is used to determine the presence of plaque.

2

Description

Prevalence of dry cavity

Timepoint
Before intervention: Assessment of the initial condition before starting to use the mouthwash. After intervention: Assessment at specific times after the start of treatment, measured on days 7 and 14.
Method of measurement
It is usually assessed through clinical records and reports of complications from patients after wisdom tooth extraction.

Secondary outcomes

1

Description
Patients' perception of pain or discomfort
Timepoint
Before the intervention: To assess the initial condition of the patients. During the intervention: Periodic assessment (every week and every month) to observe changes.
Method of measurement
It is measured through rating scales (such as a 0 to 10 rating scale) in which patients report their level of pain.

Intervention groups

1

Description
Intervention group: The effect of herbal mouthwash (propolis) is to rinse your mouth with 10 ml of mouthwash for 30 seconds, one hour after brushing your teeth, twice a day (morning and night), as recommended by the manufacturer, and avoid eating and drinking, and preferably rinsing your mouth. This should be done starting the night of surgery and continuing for two weeks.
Category
Treatment - Drugs

2

Description
Control group: Simultaneously uses chlorhexidine mouthwash. This group serves as a benchmark for comparison with the effect of propolis.
Category
Treatment - Drugs

Recruitment centers

1

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

1

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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
Hamedan 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
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Pouria Karimi
Position
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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Much of the data is potentially shareable
When the data will become available and for how long
Access to the data will be available immediately after the publication of the final article
To whom data/document is available
All researchers, researchers and clinical experts will be allowed to access the data of this study.
Under which criteria data/document could be used
It will be welcomed to conduct extensive analysis on the data of this study along with the data of other studies to write meta-analysis review articles.
From where data/document is obtainable
For more information, please send an email to Dr. Pouria Karimi. All correspondence will be sent to the email address: atmonero@gmail.com
What processes are involved for a request to access data/document
After making a phone call and submitting a request via email, the final answer will be sent within at least 1 month.
Comments