Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating and comparing the effects of chlorhexidine mouthwash and chlorhexidine-boric acid mouthwash combination on the improvement of complications following mandibular third molar surgery.

Protocol summary

Study aim

Comparing the effects of chlorhexidine mouthwash and chlorhexidine-boric acid mouthwash combination on the improvement of complications following mandibular third molar surgery.

Design

A Controlled, Single-blind, Randomized Phase 3 clinical trial on 36 patients.

Settings and conduct

In this study, 36 individuals who are candidates for impacted mandibular third molar surgery and referred to the Oral Surgery Department of the Faculty of Dentistry at the University of Medical Sciences of Kurdistan will be randomly assigned to three groups of 12 participants each. The first group will receive the combined chlorhexidine and boric acid mouthwash, the second group will receive the chlorhexidine mouthwash, and the third group will receive the placebo mouthwash. After the surgery, pain, swelling, and trismus will be assessed based on VAS, the distance from the tragus to the dental midline, the distance from the angle of the mandible to the dental midline, and inter incisal distance . .

Participants/Inclusion and exclusion criteria

Inclusion criteria : Candidates for surgery of impacted mandibular third molars who refer to the Oral Surgery Department of the Faculty of Dentistry, Kurdistan University of Medical Sciences. Exclusion criteria: The presence of mental, underlying, autoimmune and systemic diseases

Intervention groups

In This study the first Intervention Group will receive a combined mouthwash containing 0.2% chlorhexidine and 2% boric acid formulated in the Biochemistry Laboratory of Kurdistan University of Medical Sciences. second Intervention Group will receive a 0.2% chlorhexidine mouthwash، while the control group will receive a placebo mouthwash، also developed in the same laboratory. Patients will begin using the mouthwash the day after the surgical procedure and will use it twice daily.

Main outcome variables

pain, swelling, and trismus extent after mandibular third molar surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250120064446N1**
Registration date: **2025-03-07, 1403/12/17**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-07, 1403/12/17**
Update count: **0**

Registration date

2025-03-07, 1403/12/17

Registrant information

Name

Esmaeil Mohammadian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3324 4990

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-01, 1403/12/11

Expected recruitment end date

2025-05-20, 1404/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating and comparing the effects of chlorhexidine mouthwash and chlorhexidine-boric acid mouthwash combination on the improvement of complications following mandibular third molar surgery.

Public title

The impact of chlorhexidine mouthwash and chlorhexidine-boric acid mouthwash combination on complications following wisdom tooth surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Candidates for impacted mandibular third molar surgery are referred to the Oral Surgery Department of the Faculty of Dentistry, Kurdistan University of Medical Sciences.

Exclusion criteria:

The presence of mental disorders. The presence of underlying, autoimmune and systemic diseases.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will consist of three groups: - Group A: Combined mouthwash containing chlorhexidine and boric acid. - Group B: Chlorhexidine mouthwash. - Group C: Placebo mouthwash Participant allocation will be carried out using the block randomization method. The final sample size will include 36 participants. The blocks will be arranged in triplets following an A،B and C combination. A total of six blocks will be used, with the following sequence: 1:ABC 2:ACB 3:BAC 4:BCA 5:CBA 6:CAB For block selection, a random numbers table will be used. The process begins from the first number in the table, moving from left to right. When encountering a number between 1 and 6, the corresponding block is selected, while numbers outside this range are skipped.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are unaware of the type of mouthwash they will receive post-surgery.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan university of Medical Science

Street address

Pasdaran Street

City

Sanandaj

Province

Kurdistan

Postal code

6617713446

Approval date

2025-01-17, 1403/10/28

Ethics committee reference number

IR.MUK.REC.1403.253

Health conditions studied

1

Description of health condition studied

complications following mandibular third molar surgery.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The extent of pain after mandibular third molar surgery in patients using chlorhexidine mouthwash and a combination of chlorhexidine and boric acid mouthwash.

Timepoint

24 and 48 hours post surgery.

Method of measurement

Questionnaire visual analog scale

2

Description

: The extent of trismus after mandibular third molar surgery in patients using chlorhexidine mouthwash and a combination of chlorhexidine and boric acid mouthwash.

Timepoint

24 and 48 hours post surgery.

Method of measurement

Comparison of the inter incisal distance pre- and post-surgery.

3

Description
The extent of swelling after mandibular third molar surgery in patients using chlorhexidine mouthwash and a combination of chlorhexidine and boric acid mouthwash
Timepoint
24 and 48 hours post surgery.
Method of measurement
Comparison of the distances between reference points pre- and post-surgery, including the distance from the tragus to the dental midline and from the angle of the mandible to the dental midline.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Patients will receive a combined mouthwash containing 0.2% chlorhexidine and 2% boric acid. They will start using the mouthwash the day after the surgical procedure and will apply it twice daily. The mouthwash is formulated in the Biochemistry Laboratory of Kurdistan University of Medical Sciences using(Vi-One) chlorhexidine mouthwash and(Digi Shimi) boric acid 98%.
Category
Other

2

Description
Intervention group: Patients will receive a 0.2% chlorhexidine mouthwash. They will begin using the mouthwash the day after the surgical procedure and will use it twice daily. The(Vi-One) chlorhexidine mouthwash will be used
Category
Other

3

Description
Control Group: Patients will receive a placebo mouthwash. They will begin using the mouthwash the day after the surgical procedure and will use it twice daily. The placebo mouthwash is formulated in the Biochemistry Laboratory of Kurdistan University of Medical Sciences. Preparation Method: Distilled water is poured into a sterile beaker and heated to a stable temperature of 40–50°C.Polysorbate 20 is then added as a surfactant and stirred until fully dissolved .To mimic the texture and sensation of the original mouthwash, 10% ethanol and glycerin are gradually incorporated .Finally, peppermint essence is added to replicate the taste and aroma of chlorhexidine mouthwash, and food coloring is used to match its appearance.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kurdistan University of Medical Sciences, Faculty of Dentistry, Oral Surgery Department
Full name of responsible person
Dr. Hady Mohammadi
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Sponsors / Funding sources

1

Sponsor
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maleki43@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sanandaj 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
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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
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
All data is potentially shareable after unidentified individuals.
When the data will become available and for how long
Access start of published the result.
To whom data/document is available
Researchers working in academic and scientific institution.
Under which criteria data/document could be used
Researchers have access to the data under circumstances.
From where data/document is obtainable
For more information, you can contact the corresponding author via the following email. esmaeilmohammdyan@gmail,com
What processes are involved for a request to access data/document
The applicant has unlimited access to the data after sending the request via email to the corresponding

author.

Comments