Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of post-operative antibiotic administration on the complications of impacted and semi-impacted mandibular third molar surgery - a double-blinded randomized clinical trial

Protocol summary

Study aim
This study examines the effect of prophylactic amoxicillin on complications during the extraction of mandibular third molars with various anatomical variations. It also seeks to understand the use of antibiotics in this surgery and to create a protocol for standardizing their prescription.

Design
This is a Phase 2/3 randomized, double-blind, controlled trial with parallel groups involving 260 patients. The randomization method was Block randomization with blocks of 4 which used dice rolling for their arrangement.

Settings and conduct
Patients are classified into Pell & Gregory classification categories (B2 to C3) before surgery. Maximum mouth opening and soft tissue length are measured, and surgery is performed using the buccal approach after chlorhexidine rinse. Post-surgery, patients are randomly assigned to receive either 500 mg amoxicillin or placebo. They are assessed on days three and seven for mouth opening, soft tissue length, and any pus or discharge. To ensure blinding, medication or placebo is provided to patients confidentially, a third party is used to allocate the package to ensure the surgeon's blindness.

Participants/Inclusion and exclusion criteria
Samples are non-randomly selected from patients at Isfahan Dental School and the Special Clinic. Inclusion criteria are healthy individuals aged 16 to 35 with impacted or partially impacted mandibular wisdom teeth. Exclusion criteria include poor oral hygiene, ongoing antibiotic use, systemic diseases, and allergies to antibiotics, anti-inflammatories, or chlorhexidine mouthwash.

Intervention groups
The intervention group is instructed to take 15 capsules of 500 mg amoxicillin, one every 8 hours for 5 days post-surgery. The control group will receive placebo capsules following the same schedule.

Main outcome variables
Maximum mouth opening, surgical site infection, length of soft tissue from tragus to menton.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240903062941N1**
Registration date: **2024-09-14, 1403/06/24**
Registration timing: **prospective**

Last update: **2024-09-14, 1403/06/24**
Update count: **0**

Registration date
2024-09-14, 1403/06/24

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-22, 1403/07/01

Expected recruitment end date
2025-04-21, 1404/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of post-operative antibiotic administration on the complications of impacted and semi-impacted mandibular third molar surgery - a double-blinded randomized clinical trial

Public title

Investigating the effect of antibiotic administration on surgical complications of impacted and partially impacted mandibular third molars

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy individuals (ASA < 2) Age range: 16–35 years Having at least one impacted or semi-impacted wisdom tooth (categories C3, C2, C1, B3, B2 according to Pell & Gregory classification) in the mandible

Exclusion criteria:

Individuals with poor oral hygiene (OHI-S < 3) Use of an interfering antibiotic that cannot be discontinued before the study Diagnosis of a systemic disease that interferes with the healing process (based on history-taking and clinical observations) History of pericoronitis in the past 7 days Discharge of pus or serous fluid from the surgical site Use of any immunosuppressive medication History of allergic reaction to penicillin family antibiotics History of allergic reaction to ibuprofen or other NSAIDs History of allergic reaction to chlorhexidine gluconate mouthwash

Age

From **16 years** old to **35 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **260**

More than 1 sample in each individual

Number of samples in each individual: **1**

Impacted or semi-impacted mandibular third molar which falls under one of the C3, C2, C1, B3, B2 categories according to Pell & Gregory classification.

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, to balance the samples between the intervention and control groups, and considering the sample size in each of the confounding categories C3, C2, C1, B3, B2, the block randomization method is used for randomization. Accordingly, 13 blocks of 4 individuals are used for each of the mentioned categories. These 4-person blocks can be arranged in 6 different ways: (IICC, ICIC, ICCI, CIIC, CICI, CCII)*. Each of these arrangements is assigned a number from 1 to 6, and the sequence of 13 blocks in each category is determined by rolling a dice. Based on this, participants are assigned to either the intervention or control group. For instance, the following block sequence, determined by dice rolls, is one possible arrangement that can be used for randomization in categories C3, C2, C1, B3, B2: ICCI, ICIC, CCII, IICC, ICIC, CCII, CICI, CCII, CIIC, IICC, CCII, ICCI, ICIC Thus, in each of the confounding categories C3, C2, C1, B3, B2, 26 participants will be in the intervention group and 26 in the control group, resulting in a total of 130 samples in each of the overall control and intervention groups. The block sequences for each category (C3, C2, C1, B3, B2) and in general will be determined by a third party (other than the patient and the treating surgeon) as described. Accordingly, the patient will receive either a placebo or the medication. Neither the patient nor the surgeon will be informed about the block arrangement. *I = Intervention, C = Control

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind clinical trial, patients are enrolled after meeting the specified criteria. Then, based on the tooth in question, the patient is classified by the surgeon into one of the C3, C2, C1, B3, B2 categories according to the Pell & Gregory classification, using an OPG image and clinical examination. Before surgery, and during the initial evaluation, the criteria for maximum mouth opening and the length of the patient's soft tissue are assessed by the surgeon, and their status is recorded in the relevant forms. After surgery, patients from each of the C3, C2, C1, B3, B2 categories are randomly divided into the intervention and control groups by a third party using the block randomization method. Both groups are given similar packages (sealed container 49x58 with a sealed lid) containing 15 capsules. The capsules contain 500 mg of amoxicillin for the intervention group, and a similar placebo for the control group(blinding the patient by prescribing a similar capsule containing pharmaceutical grade starch placebo). Both the intervention and control groups are evaluated on the third and seventh days after surgery during follow-up sessions by a surgeon who is unaware of the substance the patient consumed(blinding of the clinical caregiver due to the presence of a third party and allocation of packages to patients by him). The evaluation includes the measurement of maximum mouth opening, following the same protocol as the initial evaluation. The length of the patient's soft tissue is also re-measured and recorded using the aforementioned method. Finally, any discharge of pus or serous fluid from the surgical site is examined and documented during these follow-up sessions through clinical examination.

Placebo

Used

Assignment

Parallel

Other design features

This study is the first and only one to investigate the prophylactic efficacy of post-operative antibiotics in various anatomical variants of the mandibular third molar, considering them as potential determining factors for the need for prophylaxis and their effect on the severity of complications. In other words, in addition to assessing the overall effectiveness of antibiotics in reducing complications from this common procedure, the study aims to develop a protocol for prescribing prophylactic antibiotics based on unmodifiable pre-operative factors (in contrast to preventable factors such as a septic environment). This would enable dentists to confidently prescribe antibiotics only where necessary and avoid unnecessary overprescription. Furthermore, the presence of these anatomical variants and their potential role in the occurrence of complications could explain the significant controversies in related studies, as none of the previous research has examined these variants separately. As a result, the outcomes may differ depending on the extent to which these variants were included in the research.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Biomedical Research of Isfahan University of Medical Sciences

Street address
Room 209 (permanent secretariat of the research ethics committee of the university),2nd floor, headquarters building No. 4, Isfahan University of Medical Sciences, Hezar Jerib St., Isfahan

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8174673461

Approval date
2024-03-13, 1402/12/23

Ethics committee reference number
IR.MUI.DHMT.REC.1402.135

Health conditions studied

1

Description of health condition studied
Surgical site infection

ICD-10 code
T81.4

ICD-10 code description
Infection following a procedure

2

Description of health condition studied
Trismus (reduction of maximum mouth opening)

ICD-10 code
R25.2

ICD-10 code description
Cramp and spasm

3

Description of health condition studied
Edema (swelling)

ICD-10 code
R60.0

ICD-10 code description
Localized edema

Primary outcomes

1

Description
Maximum mouth opening

Timepoint
Measuring the amount of maximum mouth opening at the beginning of the study (before surgery) and 3 and 7 days after extraction surgery of the impacted or semi impacted mandibular third molar

Method of measurement
For the maximum mouth opening outcome, measuring the distance between the first right incisors in a state where the patient can open his/her mouth as much as possible without pain is used with the help of a measuring gauge.

2

Description
Surgical site infection

Timepoint
Examining the discharge of pus or serous 3 and 7 days after extraction surgery of the impacted or semi impacted mandibular third molar.

Method of measurement
The discharge of pus or serous from the surgical site is examined in follow-up sessions with the help of clinical examination, and if it is positive then presence of infection is confirmed

3

Description
Length of soft tissue from tragus to menton

Timepoint
Measuring the length of soft tissue from the tragus to the menton at the beginning of the study (before the surgery) and 3 and 7 days after extraction surgery of the impacted or semi impacted mandibular third molar.

Method of measurement
For measuring the length of the patient's soft tissue, the mento-tragus length is used as an index. In this process, the two ends of the thread are passively placed on the

Menton and Tragus landmarks, then marked. Finally, the thread is transferred onto a ruler, and the distance between the two marked points is recorded in millimeters.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, for the intervention group, instructions for taking 15 amoxicillin 500mg capsules (produced by Cosar Pharmaceutical Company) are prescribed, one every 8 hours for 5 days after the operation. It should be noted that the overall intervention group actually has a sample size of 130 people which based on the controlled factor (The depth of impaction and the relation to the ramus in mandibular third molars) has been classified into 5 categories (C3, C2, C1, B3, B2) with a volume of 26 samples each. All 26 people in the intervention group of each category and accordingly all 130 overall intervention subjects receive the same medication protocol.

Category

Rehabilitation

2

Description

Control group: In this study, for the control group, the instructions for taking 15 placebo capsules (filled with pharmaceutical grade starch) are prescribed as one capsule every 8 hours for 5 days after the surgery. It should be noted that the overall control group consists of a sample size of 130 individuals, which is categorized into 5 groups (C3, C2, C1, B3, B2) based on the controlled factor (the depth of impaction and relation to the ramus in mandibular third molars), with each group containing 26 samples. All 26 participants in the control group of each category, and consequently all 130 in the overall control group, receive the same dosing protocol.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Oral and maxillofacial Surgery, Faculty of Dentistry, Isfahan University of Medical Sc

Full name of responsible person

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2

Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Esfahan 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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Mahdi Sadeghi
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Latest degree
Specialist
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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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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
Information regarding the three main outcomes, namely surgical site infection, maximum mouth opening, and the length of the soft tissue from the tragus to menton, can be shared via a comprehensive Excel file after anonymizing the individuals.
When the data will become available and for how long
The access period starts three months after the completion of the study writing and the publication of the results.
To whom data/document is available
Researchers employed at academic and scientific institutions
Under which criteria data/document could be used

Only researchers employed at academic and scientific institutions, whose job positions have been verified, can access the data tables for further analysis or aggregation with data from other studies after obtaining an ethics code from a reputable institution. The use of these documents is only permissible for examining the complications of impacted or semi-impacted mandibular third molar surgery.

From where data/document is obtainable

To access the documents, applicants must contact the responsible individuals through one of the following methods: Phone number: 09035146324 - Mr. Ali Behnam

Email 1: a.behnam1389@gmail.com - Mr. Ali Behnam

Email 2: mahdi.2313@gmail.com - Dr. Mehdi Sadeghi

What processes are involved for a request to access data/document

Applicants must send their request via email along with their job qualification documents and the ethics code related to their research. If both components are approved on the relevant websites, the data file will be sent to them via email within two weeks in accordance with the above-mentioned (in the first field) principles.

Comments