Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects of amoxicillin Prescribed and not prescribed amoxicillin on complications after mandibular impacted wisdom tooth surgery in patients without systemic problems.

Protocol summary

Study aim
Comparing the effects of prescribing amoxicillin or not prescribing it in reducing gum and wound infections; quality of wound healing; Reduction of wound inflammation after mandibular impacted wisdom tooth surgery

Design
A clinical trial with a control group with double blind parallel groups of phase 3 randomization on 40 patients

Settings and conduct
40 patients referred to Bandar Abbas Dental School in 2022 with moderate severity of impacted wisdom tooth surgery are divided into two groups of 20, one group receiving amoxicillin and the other placebo. All surgeries will be performed by one surgeon using a single protocol. The tested drugs are placed in the same boxes in the same shape. The surgeon does not know the contents of the boxes and according to the numbers assigned to the patient and the boxes, the software provides the boxes to the patient. 7 days later, the stitches are removed and the criteria for halitosis, trismus The discharge of pus from varietum will be assessed by a surgeon who is not aware of the type of antibiotic taken by the patient

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged 18 to 60 years of both sexes who agree to cooperate at the first visit and are psychologically reliable and do not have systemic problems The exclusion criteria from this study are: 1) receiving antibiotics in the last three months 2) presence of systemic diseases and pregnant women 3) The patient's sensitivity to amoxicillin

Intervention groups
Patients in two groups of 20: First group: Placebo prescription every 8 hours for 5 days. Second group: 500 mg amoxicillin prescribed every 8 hours for 5 days

Main outcome variables
Erythema, pain and trismus after wisdom tooth surgery of the lower jaw

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200705048014N2**
Registration date: **2022-09-28, 1401/07/06**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-28, 1401/07/06**
Update count: **0**

Registration date
2022-09-28, 1401/07/06

Registrant information

Name
Mohammad Reza Moaddeli

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2023-03-22, 1402/01/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of amoxicillin Prescribed and not prescribed amoxicillin on complications after mandibular impacted wisdom tooth surgery in patients without systemic problems.

Public title
Investigating the effect of amoxicillin in reducing infection after impacted wisdom tooth surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
All patients between the ages of 18 and 60, of both sexes, without systemic problems, who refer for mandibular wisdom tooth surgery.

Exclusion criteria:
The patient's lack of consent to cooperate receiving antibiotics in the last three months Failure to strictly follow the instructions after the operation Patients who have unusual problems during tooth extraction Existence of systemic diseases and pregnant women Presence of infection in the patient The patient's sensitivity to amoxicillin

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Using Sealed envelope statistical software, we perform randomization by block randomization method, blocks of 4 are divided into two groups (group A is considered intervention and group B is considered control), concealment is done by this software and the last group is not predictable. The randomization unit is individual.

Blinding (investigator's opinion)
Double blinded

Blinding description
It is explained to the patients that they will participate in an experimental study and that the prescription of antibiotics after wisdom tooth surgery is not necessary according to the dental reference books and that the boxes provided to them may contain amoxicillin or amoxicillin placebo which is similar in shape. And the size is similar to it, but the rest of the treatment process is completely similar to other patients. All surgeries will be performed by the same surgeon using the same protocol and type of flap and surgical technique, as well as the amount of bone removal.Then, using the codes given to the nurse, coded boxes will be given to the patients, which must be taken every 8 hours for 5 days. Amoxicillin and placebo capsules are the same in terms of shape, color and size and in the same packaging. 7 days later, patients will be examined by the surgeon who performed the surgery.

Placebo
Used

Assignment
Parallel

Other design features
The number of 40 patients without systemic disease, not taking drugs that interfere with the tested drugs and psychotic drugs, as well as the presence of a mandibular wisdom tooth with a moderate degree of difficulty will be included in the study. Patients in two groups of 20: First group: Placebo prescription every 8 hours for 5 days.The second group: Amoxicillin 500 mg every 8 hours for 5 days.Patients are randomly divided by PASS software. All surgeries will be performed by one surgeon using the same protocol and type of flap and surgical technique as well as the amount of bone removal. The tested drugs, including amoxicillin and placebo amoxicillin, are placed inside the same boxes, and the patient will be instructed to use them by a colleague who is not aware of the contents of the boxes. It is explained to the patients that in case of any special problem or evidence of infection, they should call or refer to the hospital, otherwise, they should return for examination 7 days after the surgery.In this follow-up session, the sutures are removed and the parameters of halitosis and pus discharge are examined, and the amount of erythema will be evaluated qualitatively based on the extent and intensity of redness. The severity of trismus is evaluated by measuring the distance between the incisor teeth at the maximum opening of the patient's mouth using a gauge. All clinical evaluations will be measured by a surgeon who is not aware of the type of antibiotic taken by the patient.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hormozgan University of Medical Sciences

Street address
Shariati Dental Clinic, Nasser Blvd

City
Bandar abbas

Province
Hormozgan

Postal code
1468613684

Approval date
2022-07-30, 1401/05/08

Ethics committee reference number
IR.HUMS.REC.1401.129

Health conditions studied

1

Description of health condition studied
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
wound healing process
Timepoint
7 days after surgery
Method of measurement
Clinical examination of the wound

2

Description
pain after surgery
Timepoint
Daily up to 7 days after surgery
Method of measurement
Question from the patient and rating from 1 to 5

Secondary outcomes

1

Description
Erythema in the area
Timepoint
7 days after surgery
Method of measurement
Physical examination

2

Description
halitosis
Timepoint
Daily until seven days after surgery
Method of measurement
Ask the patient

3

Description
Trismus
Timepoint
7 days after surgery
Method of measurement
Clinical examination using a ruler with millimeter unitsCommunity Verified icon

Intervention groups

1

Description
Mandibular impacted wisdom tooth surgery of class 1B type, which has moderate difficulty, is performed for patients with a similar protocol that includes the removal of a small amount of bone (less than 3 mm) by a surgical bur, tooth loosening with an elevator, and extraction with forceps. It should be noted that the instruments were thoroughly checked for sterility and all the instruments will be sterile and all procedures will be performed with sterile surgical gloves. After the surgery, the intervention group received amoxicillin 500 mg boxes made by Dana Pharmaceutical Company every 8 hours. It will be received for 5 days
Category
Treatment - Drugs

2

Description
Control group: Mandibular impacted wisdom tooth surgery of type 1B, which has moderate difficulty, with a similar protocol that includes the removal of a small amount of bone (less than 3 mm) by surgical bur, tooth loosening with elevator and extraction with forceps for patients is done.It should be noted that the instruments were thoroughly checked for sterility and all the instruments will be sterile and all the procedures will be performed with sterile surgical gloves. day will be used.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Bandar Abbas Faculty of Dentistry
Full name of responsible person
Fariba Habibi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas University of Medical Sciences

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?
No

Title of funding source
student

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Mohammadreza Moaddeli

Position
associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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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 playable after de-identifying participants

When the data will become available and for how long

6 months after registering the results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Systematic review articles

From where data/document is obtainable

Email:faribahabiby@gmail.com Its owner is Fariba Habibi

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

Send email

Comments