

# 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)

##### Phone

+98 76 3335 0458

##### Email address

m.moaddeli@hums.ac.ir

##### 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

##### Street address

Nasser Boulevard, Shariati Hospital, Bandar Abbas  
School of Dentistry

##### City

Bandar Abbas

##### Province

Hormozgan

##### Postal code

1468613684

##### Phone

+98 939 479 0860

##### Email

faribahabiby@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Dr Mohammadreza Moaddeli

**Street address**

Nasser Boulevard, Shariati Hospital, Bandar Abbas  
School of Dentistry

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

1468613684

**Phone**

+98 939 479 0860

**Email**

faribahabiby@gmail.com

**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

**Street address**

Nasser Boulevard, Shariati Hospital, Bandar Abbas  
School of Dentistry

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

1468613684

**Phone**

+98 939 479 0860

**Email**

faribahabiby@gmail.com

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Moaddeli

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Imam Khomeini Blvd.

**City**

Badar Abbas

**Province**

Hormozgan

**Postal code**

1468613684

**Phone**

+98 76 3335 0458

**Fax****Email**

m.moaddeli@hums.ac.ir

### Person responsible for updating data

**Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Moaddeli

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Imam Khomeini Blvd.

**City**

Badar Abbas

**Province**

Hormozgan

**Postal code**

7919915519

**Phone**

+98 76 3335 0458

**Fax****Email**

m.moaddeli@hums.ac.ir

### 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**