

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of two drugs in controlling pain and swelling after open sinus lift surgery(clinical trials)

Protocol summary

Study aim

Comparison of two drugs in controlling pain and swelling after open sinus lift surgery(clinical trials)

Design

Phase three clinical trial with control group. With parallel groups. Two blind strains, randomized into two groups

Settings and conduct

This study is a double-blind clinical trial on 90 patients referred to the surgical department of the dental school Islamic Azad University and a candidate for open sinus lift surgery was performed in 1399

Participants/Inclusion and exclusion criteria

1. range ages 18-40 2. informed consent 3. Candidate for open sinus lift surgery 1 !. Pregnancy and lactation 2. Tobacco consumption 3. Immune system defects

Intervention groups

Ninety patients who referred to Tehran Azad School of Dentistry were randomly divided into two groups of 45 patients. Participants in the study should be available at the times needed to assess pain control (by telephone) and edema control (in person). Otherwise excluded from the investigation. The selection of samples continued until the desired quorum was reached. The case group was treated with 500 mg amoxicillin and 200 mg curcumin after surgery. In the control group, participants in the study were given 500 mg of mefenamic acid and 500 mg of amoxicillin after surgery. All tablets were packaged in the same coating and there was no difference between the appearance of the drugs in either group.

Main outcome variables

Control of pain and swelling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210215050366N1**

Registration date: **2021-02-21, 1399/12/03**

Registration timing: **prospective**

Last update: **2021-02-21, 1399/12/03**

Update count: **0**

Registration date

2021-02-21, 1399/12/03

Registrant information

Name

Somayeh Alirezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2282 1160

Email address

s.alirezaei@iautmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-28, 1399/12/10

Expected recruitment end date

2021-03-14, 1399/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two drugs in controlling pain and swelling after open sinus lift surgery(clinical trials)

Public title

Comparison of two drugs in controlling pain and swelling

after open sinus lift surgery(clinical trials)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

18-40 age Informed consent

Exclusion criteria:**Age**

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are selected by available and non-probabilistic methods and from among them, patients who meet the inclusion criteria will be selected. Then patients will be divided into two groups of control and intervention by simple random method (code is assigned to each sample) and using SPSS statistical software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients are unaware of which treatment group they are. The outcome measurer is different from whom that cures patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Islamic Azad University of Medical Sciences, Tehran

Street address

Pasdaran Ave.neyestan 9th,Tehran Azad Dental School

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2020-11-10, 1399/08/20

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.225

Health conditions studied**1****Description of health condition studied**

Control of pain and swelling after open sinus lift surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Control of pain and swelling after open sinus lift surgery

Timepoint

Repeat doses of the drug every 8 hours for 7 days

Method of measurement

Visual pain scale (Visual analogue scale) was used to evaluate the pain experienced by participants in the study. Swelling was measured in millimeters using a ruler. Thus the distance of the ear tragus with The lower lip angle was measured before surgery and was considered as a reference for cheek swelling. Then this interval was measured on days 1, 2 and 3 after the operation and its difference with this interval before the operation was considered as a criterion for examining the swelling and thus the amount of swelling was obtained. Inflation rateIt was measured by the researcher in charge of filling out the questionnaire and information forms

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Control group: Participants in the study were given 500 mg of mefenamic acid and 500mg of amoxicicillin after surgery.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Department of Surgery, School of Dentistry, Islamic Azad University of Tehran

Full name of responsible person

Mohammad anvari digeh sara

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

arash azizi

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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

Islamic Azad University

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad anvari digeh sara

Position

Student

Latest degree

Medical doctor

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)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available