Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The role of postoperative antibiotics in prevention of infection at open reduction of mandibular compound fractures

Protocol summary

Summary

(1) Objectives; The aim of this study is the role of postoperative antibiotics in prevention of infection in open reduction of mandibular compound fractures. (2) Design; This study is a Randomized, double blind, placebo controlled clinical trial. (3) Setting and conduct; 80 Patients diagnosed with open fractures of the mandible were placed on two groups: Antibiotic group or non antibiotic group and they receive 2-5 day preoperatively 1gr Cefazolin IV qid. Antibiotics 1gr Cefazolin IV was continued for 30 minutes before surgery. At the time of the surgery all the patients received intraoperative antibiotics which consisted of Cefazolin IV 1gr (900 mg clindamycin IV if allergic to penicillin). At the conclusion if the procedure is going to take more than 5 hours the patients would receive 1gr Cefazolin IV. At the end of the surgery the patients were randomized into 2 groups (antibiotic group and non antibiotic group). (4) Participants including major eligibility criteria; The main inclusion criteria consists of at least 1 fracture of mandible and open reduction and internal fixation. Exclusion criteria are presence of an acute bacterial infection, fracture of the skull base and Inter Maxillary Fixation. (5) Intervention; The antibiotic group receive 600mg Clindamycin IV tds 7 days postoperative with chlorhexidine gluconate 0.12% oral rinse. The drug company is Dana Tabriz, Iran. The non antibiotic group receive placebo drug for 7 days with chlorhexidine gluconate 0.12% oral rinse. (6) main outcome measures; Patients were examined at 1, 3 and 5 weeks for signs and symptoms of infection using the following clinical criteria: Infection, Erythema, Drainage, Fever.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041521787N1**

Registration date: **2015-09-14, 1394/06/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-14, 1394/06/23

Registrant information

Name

Minou Najarnobari

Name of organization / entity

Tehran university of medical science, dental school

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2015-09-11, 1394/06/20

Expected recruitment end date

2016-09-10, 1395/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of postoperative antibiotics in prevention of infection at open reduction of mandibular compound fractures

Public title
The role of antibiotics in mandibular fractures
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Open reduction and internal fixation; At least 1 fracture of mandible; Follow up of at least 5 weeks. Exclusion criteria: Infection during surgry; Gunshot wounds; Need for intensive care; Presence of an acute bacterial infection; Pathological fractures; Fracture of the skull base; History of malignancy/ radiation of the head and neck area; Immunosuppression; Reduced body weight; Kidney disease; Inter Maxillary Fixation; Insufficient follow up
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran university of medical science
Street address
Ghods central building, Ghods street, Keshavarz street, Tehran, Iran
City
Tehran
Postal code
Approval date
2015-06-16, 1394/03/26
Ethics committee reference number
IR.TUMS.REC.1394.54

Health conditions studied

1

Description of health condition studied
Mandibular fracture
ICD-10 code
S02.6
ICD-10 code description
Lower jaw (bone)

Primary outcomes

1

Description
Infection
Timepoint
Follow up appointments were 1,3,5 weeks postoperatively
Method of measurement
Infection, Inflammation, Erythema, Fever, Drainage

Secondary outcomes

empty

Intervention groups

1

Description
Patients diagnosed with open fractures of the mandible were placed on two groups: Antibiotic group or non antibiotic group and they receive 2-5 day preoperatively 1gr Cefazolin IV qid. Antibiotics 1gr Cefazolin IV were continued for 30 minutes before surgery. At the time of the surgery all the patients received intraoperative antibiotics which consisted of Cefazolin IV 1gr (900 mg clindamycin IV if allergic to penicillin). At the conclusion if the procedure is going to take more than 5 hours the patients would receive 1gr Cefazolin IV. At the end of the surgery the patients were randomized into 2 groups (antibiotic group and non antibiotic group). The antibiotic group receive 600mg Clindamycin IV tds 7 days postoperative with chlorhexidine gluconate 0.12% oral rinse. The drug company is Dana Tabriz, Iran.
Category
Treatment - Drugs

2

Description
Patients diagnosed with open fractures of the mandible were placed on two groups: Antibiotic group or non antibiotic group and they receive 2-5 day preoperatively 1gr Cefazolin IV qid. Antibiotics 1gr Cefazolin IV were continued for 30 minutes before surgery. At the time of the surgery all the patients received intraoperative antibiotics which consisted of Cefazolin IV 1gr (900 mg clindamycin IV if allergic to penicillin). At the conclusion if the procedure is going to take more than 5 hours the patients would receive 1gr Cefazolin IV. At the end of the surgery the patients were randomized into 2 groups (antibiotic group and non antibiotic group). The non Ab

group receive placebo drug for 7 days with chlorhexidine gluconate 0.12% oral rinse.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Shariati hospital

Full name of responsible person

Dr Mehrnoush Momeni Rouchi

Street address

Dr Shariati hospital, Nasr bridge, Kargar street, Tehran, Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Dr Mehrnoush Momeni Rouchi

Street address

Sina hospital, Hassan Abad street, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr Amirreza Rokn

Street address

Tehran Dentistry school, kargar street, Hakim street, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran university of medical science

Full name of responsible person

Dr. Mehrnoush Momeni Rouchi

Position

DDS; MDS

Other areas of specialty/work

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Dental School of Tehran university of medical science, Hakim street, Kargar street, Tehran, Iran

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Other areas of specialty/work

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Name of organization / entity

Dental school of Tehran university of medical science

Full name of responsible person

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Position

Student at dental school of Tehran university of medical science

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty