

How effective are antibiotics in preventing postoperative complications in patients after tooth extraction surgery?

Submission date 16/12/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/12/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/12/2018	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Despite evidence that antibiotics abuse is related to unknown pathogen infection, antibiotics are badly overused in China, as common people can easily buy antibiotics in pharmacy stores, even without prescriptions from doctors. The necessity and feasibility of antibiotics treatment after tooth extraction surgery, among the most common surgical operations, remain unclear. In order to ensure that the efficacy of antibiotics treatment in preventing postoperative complications in patients after tooth extraction surgery. We prescribe antibiotics for patients after tooth extraction. Then we invite them to have an examination about the wound to assess the degree of pain, swelling, opening degree and alveolitis. This study aims to recruit 200 blood donors to compare different intervals between patients with tooth extraction. The goal is to find the optimum interval for which it is safe for patients with tooth extraction.

Who can participate?

Adults over the age of 17 who have pericoronitis in the distal aspect of a third molar and are willing to have the tooth extracted at Nanjing University of Science and Technology Hospital.

What does the study involve?

Participants are asked to join this study while they are at Hospital of Nanjing University of Science and Technology in China. Participants must be over the age of 17 and have infection in the last molars. Participants are randomly allocated to one of two groups. Those in the first group as asked to take amoxicillin 0.5g/ and metronidazole 0.2g one hour postoperatively (three times every day) after tooth extraction. Those in the second group are asked to take a placebo with the same shape and dose on the same times. The study lasts for 7 days. Participants are asked to go back to check the wound in tooth extraction.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part. By taking part in this study there are no risks of physical injury or harm.

Where is the study run from?

The INTERVAL study is being run by the Nanjing University of Science and Technology and takes place in Hospital of Nanjing University of Science and Technology.

When is the study starting and how long is it expected to run for?

June 2015 to December 2017

Who is funding the study?

Wuxi Young Medical Talents (China) (No. QNRC095)

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

0000-0001-5194-8131

Study information

Scientific Title

Efficacy of antibiotics treatment in preventing postoperative complications in patients after tooth extraction surgery: a prospective, randomized, double-blind controlled study

Study objectives

Using antibiotics after tooth extraction surgery does not provide additional benefits to Chinese population.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Institutional Review Board of Nanjing University of Science and Technology, 22/06/2015.

Study design

Single-centre prospective, randomized, double-blind controlled study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Pericoronitis

Interventions

Patients in the treatment group took amoxicillin 0.5g/ and metronidazole 0.2g one hour postoperatively (three times every day) for three days after tooth extraction. Patients in the placebo group took a placebo with the same shape and dose on the same times. Pain, swelling, mouth opening degree, and Alveolitis events were assessed at 7th days after tooth extraction.

Bilateral molars in each group was were randomly assigned to two groups using a randomization software (version 1.0; Random Allocation Software, Isfahan, Iran)

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Amoxicillin and metronidazole

Primary outcome(s)

1. Pain was measured using a visual analogue score (VAS) at 7th days after tooth extraction.
2. Swelling was measured as the difference between the distance (mm) between the lower earlobe and the mesomental line on the extraction side at 7th days after tooth extraction.
3. Mouth opening degree was measured as the distance between upper and lower incisors at 7th days after tooth extraction.

Key secondary outcome(s)

Alveolitis event was diagnosed by a dry appearance of the exposed bone in the socket after trauma.

Completion date

31/01/2018

Eligibility

Key inclusion criteria

Current inclusion criteria:

1. Have pericoronitis in the distal aspect of a third molar and pericoronitis-related lymphadenopathy.
2. Have indication for extraction of the third molars due to recurrent infections (at least two times) occurred at certain intervals.
3. Had tooth in the vertical position.
4. Had operculum covering 1/2–2/3 of the outer surface of the tooth.

Previous inclusion criteria:

1. Have pericoronitis in the distal aspect of the mandibular third molars and pericoronitis-related lymphadenopathy.
2. Have indication for extraction of the third molars due to recurrent infections (at least two times) occurred at certain intervals.
3. Had tooth in the vertical position.
4. Had operculum covering 1/2–2/3 of the outer surface of the tooth.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Have a systemic disease
2. Pregnant women or women having suspicion of pregnancy
3. Lactating women
4. Received bisphosphonate at any time
5. Received antibiotic or anti-inflammatory drugs within the last month

Date of first enrolment

01/07/2015

Date of final enrolment

31/12/2017

Locations

Countries of recruitment

China

Study participating centre
Hospital of Nanjing University of Science and Technology
No.200 Xiaolingwei Street, Xuanwu District
Nanjing
China
210094

Sponsor information

Organisation
Hospital of Nanjing University of Science and Technology

ROR
<https://ror.org/00xp9wg62>

Funder(s)

Funder type
Other

Funder Name
Wuxi Young Medical Talents (China) (No. QNRC095).

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date