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

Submission date
16/12/2018

Recruitment status
No longer recruiting

Registration date
18/12/2018

Overall study status
Completed

Last Edited
19/12/2018

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 then 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 took 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 took 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format,please use contact details to request a partciapnt information sheet

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 measure
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 mesomentum 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.

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

Overall study start date
01/03/2015

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

Age group
Adult

Sex
Both

Target number of participants
200

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

Sponsor details
Hospital of Nanjing University of Science and Technology, 200 xiaoling wei street, xuanwu district Nanjing Jiangsu, 210049, China.
Nanjing
China
210094

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00xp9wg62

Funder(s)

Funder type
Other

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

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/09/2019

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