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The effect of ibuprofen on postoperative pain reduction following mini-screw insertion for orthodontic treatment

Submission date
16/12/2024

Recruitment status
No longer recruiting

Registration date
20/12/2024

Overall study status
Completed

Last Edited
19/02/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The present study aims to investigate the clinical efficacy of orally administered ibuprofen sustained-release capsules in providing preemptive analgesia during orthodontic mini-screw insertion for patients with malocclusion. The objective was to evaluate the impact of preoperative ibuprofen administration on postoperative pain following the insertion of a single posterior orthodontic mini-screw. This study endeavors to contribute to the body of knowledge regarding optimal pain management strategies for such procedures, aiming to enhance patient comfort and satisfaction during orthodontic treatment.

Who can participate?
Adult patients aged 18 to 50 years old requiring the insertion of a single mini-screw for orthodontic treatment

What does the study involve?
The experimental group received 300 mg of ibuprofen sustained-release capsules orally 30 minutes prior to surgery, while the control group received a placebo under the same conditions. Postoperative pain scores were recorded at 2, 4, 6, 8, 12, and 24 hours after surgery, and the amount of analgesic medication self-administered by patients within 24 hours was also documented.

What are the possible benefits and risks of participating?
Participants may help develop a safer and more effective form of pain relief. Risks include possible side effects of pain medication.

Where is the study run from?
Wuhan University Dental Hospital (China)

When is the study starting and how long is it expected to run for?
February 2024 to December 2024

Who is funding the study?
The National Natural Science Foundation of China

Who is the main contact?
Yang Wu, wuyang83@whu.edu.cn

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
The National Natural Science Foundation of China Grant No. 31400836

Study information

Scientific Title
A randomized controlled trial assessing the effect of preoperative ibuprofen administration on postoperative pain reduction following mini-screw insertion for patients with malocclusion

Study objectives
Preoperative ibuprofen administration can reduce postoperative pain following mini-screw insertion for patients with malocclusion

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/05/2024, The Ethics Committee of School & Hospital of Stomatology, Wuhan University (3F, Center Laboratory, Han University Dental Hospital, 237 Luoyu Road, Wuhan, 430079, China; 027-87686250; wdkqllwyh@163.com), ref: [WDKQ2024] LUNSHEN (B46)

Primary study design
Interventional

Study design

Single-center intervention single-blind randomized controlled trial

Study type(s)
Diagnostic, Treatment

Health condition(s) or problem(s) studied
Postoperative pain following mini-screw insertion for patients with malocclusion

Interventions
This study is a single-center intervention single-blind randomized controlled trial. Patients enrolled will be randomly assigned to two groups: an experimental and a control group. The experimenter used SAS software (9.4, USA) to generate a random number for each patient, then sorted the generated random numbers, and based on the sorting results, patients in the first half of the sorting were assigned to the experimental group, and those in the second half of the sorting were assigned to the control group, making sure that there were equal numbers of patients in each group, and recording the results of randomization. According to the randomization results, different drugs were packaged and distributed to patients in each group before surgery, and the drugs in both groups were in the same capsule dosage form with the same appearance.

The experimental group will receive 300 mg of ibuprofen sustained-release capsules orally 30 minutes before surgery. The control group will receive a placebo capsule (300 mg/capsule, filled with starch) orally before surgery. Pain Relief Medication: Following surgery, subjects can self-administer ibuprofen sustained-release capsules based on their pain levels (reaching a Numerical Rating Scale (NRS) score of 3), while documenting the frequency and timing of administration.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ibuprofen sustained-release capsules

Primary outcome(s)
Pain is measured using a Numerical Rating Scale (NRS) at baseline, 2, 4, 6, 8, 12, and 24 hours

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
15/12/2024

Eligibility

Key inclusion criteria
1. Age range: 18 to 50 years old, inclusive
2. Absence of cardiopulmonary diseases, normal liver and kidney function, no history of abnormal bleeding or coagulation disorders

3. No use of analgesic, anti-inflammatory, or anticoagulant medications within one week before surgery
4. Requirement for the insertion of a single mini-screw for orthodontic treatment, with no need for other oral surgeries apart from orthodontic interventions
5. Normal bone density at the insertion site confirmed by cone-beam computed tomography (CBCT)
6. Voluntary participation in the study and completion of the survey questionnaire

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
All

Total final enrolment
68

Key exclusion criteria
1. Pregnant or lactating women
2. Presence of systemic diseases such as coagulation disorders, cardiovascular and cerebrovascular diseases, or endocrine disorders
3. Allergic to the medication ibuprofen and the intraoperative medication articaine hydrochloride used in this study
4. Untreated dental pain conditions such as pulpitis, apical periodontitis, or trigeminal neuralgia requiring long-term analgesic use
5. Concurrent acute oral infections or tumors
6. Alcohol consumption within one week before surgery
7. Active or past history of peptic ulcer, gastrointestinal bleeding, or perforation
8. Current use of ibuprofen, selective cyclooxygenase-2 (COX-2) inhibitors, or other NSAIDs
9. Prior history of mini-screw insertion surgery

Date of first enrolment
06/05/2024

Date of final enrolment
15/12/2024

Locations

Countries of recruitment
China

Study participating centre
Wuhan University Dental Hospital
237 Luoyu Road
Wuhan
China
430079

Sponsor information

Organisation
Wuhan University Dental Hospital

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/02/2025	19/02/2025	Yes	No