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Effects of compound chamomile lidocaine gel after mandibular third molar surgeries

Submission date 03/06/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 19/06/2026	**Overall study status** Completed	
Last Edited 19/06/2026	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific

Contact name
Dr Yang Wu

ORCID ID
https://orcid.org/0000-0002-4882-5584

Contact details
Department of Oral & Maxillofacial Surgery, School & Hospital of Stomatology, Wuhan University
Wuhan
China
430079
+86 13720390002
wuyang83@whu.edu.cn

Type(s)
Public

Contact name
Miss Meng-Di Nie

Contact details
State Key Laboratory of Oral & Maxillofacial Reconstruction and Regeneration, Key Laboratory of Oral Biomedicine Ministry of Education, Hubei Key Laboratory of Stomatology, School & Hospital of Stomatology, Wuhan University

Wuhan
China
430079
+86 18286842858
xndm688@163.com

Additional identifiers

Study information

Scientific Title
Effects of compound chamomile lidocaine gel after mandibular third molar surgeries: a double-blind randomised controlled trial

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/03/2026, The Ethics Committee of the School & Hospital of Stomatology, Wuhan University (No. 237, Luoyu Road, Hongshan District, Wuhan, 430079, China; +86 27-87686250; wdkqllwyh@163.com), ref: [WDKQ2026]B27

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Analgesic effect of compound chamomile lidocaine gel after third molar extraction

Interventions

The statistician uses EXCEL to generate a random sequence in advance, then writes each group result on separate slips of paper and places them in envelopes that are identical in appearance, opaque, and numbered in order. The envelopes are sealed and stored in consecutive numerical order. When a patient is enrolled, the researcher opens the next envelope in sequence and carries out the group assignment specified inside the envelope. The numbering must be consecutive and cannot be skipped. Envelopes can only be opened when a patient is enrolled and must not be opened prematurely.

According to the randomization results, after surgery, the experimental group's extraction sockets are filled with compound chamomile lidocaine gel, then sutured and compressed for hemostasis, while the control group's extraction sockets are filled with a placebo, then sutured and compressed for hemostasis. Both groups are instructed to take oral ibuprofen as needed for pain after surgery, and the frequency of analgesic use is recorded.

Follow up for 7 days.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Compound Chamomile Lidocaine Gel (Kamistad gel)

Primary outcome(s)
1. NRS Pain Score measured using NRS Pain Assessment Questionnaire at 2 hours, 6 hours, 12 hours after surgery, 1 day, 2 days, 3 days, 5 days, 7 days after surgery

Key secondary outcome(s)
1. Frequency and dosage of painkillers measured using Questionnaire at Within 7 days after surgery

2. The degree of facial swelling measured using The tape measure method described by Gabka and Matsumara at The third day after surgery

Completion date
07/03/2026

Eligibility

Key inclusion criteria
1. Age range: 18-50 years
2.no mouth opening restrictions, no cardiovascular or pulmonary diseases, normal liver and kidney function, no history of abnormal bleeding or coagulation disorders, or other contraindications to tooth extraction
3.Based on the combination of the Winter classification and the Pell & Gregory classification, we included mandibular third molars of classes IA, IB, IIA, IIB vertical, and IIA mesioangular impactions. All types of wisdom teeth surgeries were completed within 30 minutes by experienced doctors after evaluating imaging and oral examinations
4. The patient is in good overall health, with no systemic diseases (ASA I/II)

5. Voluntarily participates in the study and completes the questionnaire, and has signed the informed consent form and committed to follow-up

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
All

Total final enrolment
37

Key exclusion criteria
1. Menstruating women, pregnant women, or breastfeeding women
2. Presence of systemic diseases, such as coagulation disorders, cardiovascular and cerebrovascular diseases, or endocrine diseases
3. Allergy to chamomile, lidocaine, or intraoperative use of artemisinin hydrochloride used in this study
4. History of taking any analgesics within the past week, or long-term medication use
5. Presence of untreated dental pain conditions, such as pulpitis, periodontitis with apical inflammation, or trigeminal neuralgia, requiring long-term analgesia
6. History of invasive dental treatment within the past week
7. Concurrent acute oral infection or tumor
8. Alcohol consumption within one week before surgery
9. Active or past history of digestive ulcers, gastrointestinal bleeding, or perforation;
10. Currently using ibuprofen, selective cyclooxygenase-2 (COX-2) inhibitors, or other non-steroidal anti-inflammatory drugs;
11. History of previous surgery.

Date of first enrolment
20/07/2024

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
China

Sponsor information

Organisation
Accademia di Belle Arti di Frosinone

ROR
https://ror.org/03ekjqb98

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available