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Pain management after immediate implant placement

Submission date	Recruitment status	[_] Prospectively registered
21/07/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/07/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/07/2026	Oral Health	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
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Additional identifiers

Study information

Scientific Title
Application of liposomal bupivacaine in pain management after immediate implant placement

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/08/2025, Ethics Committee of Changshu Yuhui Dental Hospital (No. 77, New Century Avenue, Changshu, 215500, China; +86 (0)512 52179817; beesugara_fm@outlook.com), ref: No. 2025-Lunshen-002

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Postoperative pain management in patients undergoing immediate dental implant placement (≤3 implants)

Interventions
Participants were randomly assigned to an experimental group (n=16) and a control group (n=16) using a random number table. The specific steps for randomization and allocation concealment were as follows: 1. Random Sequence Generation: A research assistant (not involved in clinical procedures or evaluations) generated a random number sequence for patients numbered 132 using SPSS 22.0 software; 2. Allocation Concealment: Based on the random allocation sequence, group information (the experimental group or control group) was placed into sequentially numbered, sealed, and opaque envelopes (SNOSE method). These envelopes were kept by designated personnel to ensure that the clinical physicians, evaluators, and patients could not access group information before patient enrollment and signing of informed consent forms; 3. Implementation of Randomization: After enrollment, patients were numbered in the order of their inclusion. A surgical assistant sequentially opened the corresponding numbered envelope, assigned the patients to the experimental or control group following the instructions inside the envelope, and then notified the operating physician to execute the corresponding analgesic protocol.

Experimental group:
Routine articaine anaesthesia was implemented. After surgery, 3–5 ml of 1.3% liposomal bupivacaine was injected subperiosteally and around incisions: 3 ml for a single implant, 4–5 ml for 2–3 implants, with local compression for 1–2 min after injection.

Control group:
Only routine articaine anaesthesia was used without postoperative long-acting local anaesthetic.

Surgical procedures were identical in the two groups.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Liposomal bupivacaine

Primary outcome(s)
1. Postoperative pain severity measured using the Visual Analogue Scale (VAS) for pain, a 0–10 point scale, at 24 hours postoperatively (24 h after surgery)

Key secondary outcome(s)

Completion date
28/02/2026

Eligibility

Key inclusion criteria
1. ≤3 immediate implants with intact socket bone wall
2. Aged 18–70 years, American Society of Anesthesiologists (ASA) I–II
3. No local anaesthetic or nonsteroidal anti-inflammatory drug (NSAID) allergy
4. Complete 72-h follow-up
5. Voluntary informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
32

Key exclusion criteria
1. Women who are pregnant or lactating
2. Severe cardiopulmonary, hepatic or renal disease, coagulation disorders or uncontrolled diabetes (fasting blood glucose >8.0 mmol/l)
3. Combined bone grafting and sinus elevation
4. Long-term analgesic or hormone dependence
5. Patients with psychiatric disorders who are unable to cooperate
6. Acute or chronic inflammation of the surgical site

Date of first enrolment
01/09/2025

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
China

Sponsor information

Organisation
Changshu Yuhui Dental Hospital

Funder(s)

Funder type

Funder Name
Changshu Yuhui Dental Hospital

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available