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Testing two pain relief methods before and after surgery for people having keyhole liver operations

Submission date
16/12/2025

Recruitment status
No longer recruiting

Registration date
18/12/2025

Overall study status
Completed

Last Edited
17/12/2025

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looks at ways to improve pain relief for people having keyhole liver surgery (called laparoscopic liver resection). Although this type of surgery usually means less blood loss and a quicker recovery than traditional open surgery, patients can still have a lot of pain afterward. Good pain control helps people feel more comfortable, move around sooner, and recover faster. The study will test whether giving a pain medicine called nalbuphine before surgery, combined with a nerve block called a TAP block after surgery, works better than standard pain treatment or the TAP block alone.

Who can participate?
Adults aged 18 to 70 who are scheduled for keyhole liver surgery to remove benign or cancerous liver growths can take part. Participants need to be able to give informed consent and must not have allergies or other problems with the medicines or procedures used in the study.

What does the study involve?
People who join will be randomly placed into one of three groups:
-Standard care group: receives usual pain treatment after surgery.
-TAP block group: receives a TAP block after surgery plus standard care.
-Combined group: receives nalbuphine before surgery and a TAP block after surgery plus standard care.

Everyone will be monitored for pain levels, side effects, and recovery progress. Pain will be measured using a simple scale, and the amount of pain medicine used will be recorded. Recovery measures like time to first movement and hospital stay will also be tracked.

What are the possible benefits and risks of participating?
Benefits may include better pain control, less need for extra pain medicine, and faster recovery. Risks include possible side effects from nalbuphine, such as nausea or dizziness, and minor risks from the TAP block, like temporary numbness or infection at the injection site. All procedures will be done safely and monitored closely.

Where is the study run from?
The study is being carried out at Huizhou Central People’s Hospital, which has experience in liver surgery and anesthesia.

When is the study starting and how long is it expected to run for?
The study started in September 2024 and will run for about 12 months.

Who is funding the study?
The study is funded by the Science and Technology Planning Project of Huizhou City, Guangdong Province. The funder does not influence the study design or results.

Who is the main contact?
For more information or to ask about joining the study, contact Jinchao Wang at hehe_ff@163.com

Contact information

Type(s)
Scientific, Public, Principal investigator

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Study information

Scientific Title
Efficacy and safety of nalbuphine preemptive analgesia combined with subcostal transversus abdominis plane block for postoperative pain management in patients undergoing laparoscopic liver resection: a prospective, randomized, double-blind, controlled trial

Acronym
NAP-TAPB LLR Study

Study objectives

To explore the application effect of preemptive analgesia with nalbuphine combined with subcostal transverse abdominis plane block(TAPB) in laparoscopic hepatectomy (LLR), and to provide an optimized scheme for postoperative analgesia.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 13/06/2024, Huizhou Central People's Hospital (Huizhou City, Guangdong Province, Huizhou, 516002, China; +86-07522288662; huizhou_iec@126.com), ref: KY112024085

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Basic science, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Postoperative pain management in patients undergoing laparoscopic liver resection (LLR) due to benign and malignant liver lesions

Interventions
C group: Administer physiological saline 0.1ml/kg 15 minutes before anesthesia induction, and anesthetize according to the anesthesia protocol.
TAPB group: Administer 0.1ml/kg physiological saline 15 minutes before anesthesia induction; Anesthetize according to the anesthesia plan. After the surgery, TAPB was performed through bilateral subcostal approaches under ultrasound guidance.
N+TAPB group: Patients received intravenous nalbuphine (0.1 mg/kg) 15 minutes before anesthesia induction, followed by the standard anesthetic protocol.

Patients were randomly allocated to three groups (1:1:1 ratio) using a computer-generated random number table. Allocation was concealed via a pre-prepared randomization sequence maintained by an independent researcher. While the intervention team was aware of group assignments, outcome assessors used standardized, blinded assessment tools (e.g., NRS, BCS scores) to minimize bias.

Intervention Type
Mixed

Primary outcome(s)
1. Analgesic effect measured using Numerical Rating Scale, Bruggrmann Comfort Scale, Ramsay Scale at postoperative 2, 8, 12, and 24 hours

Key secondary outcome(s))
1. Postoperative opioid consumption measured using total morphine equivalent dose (mg) calculated from patient-controlled analgesia (PCA) records or nurse-administered analgesic records at during the first 24 hours postoperatively

2. Quality of recovery score measured using quality of Recovery-15 (QoR-15) questionnaire at on postoperative day 1 (POD1) and postoperative day 2 (POD2)

Completion date
15/12/2025

Eligibility

Key inclusion criteria
1. American Association of Anesthesiologists (ASA) grade I~III, age 18~70 years old, body mass index (BMI) 20 ~ 25 kg/m²
2. Preoperative laboratory tests such as liver and kidney function, coagulation function, etc. were basically normal
3. The abdominal skin is not damaged or infected

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
180

Key exclusion criteria
1. Cardiovascular and cerebrovascular diseases or liver, kidney and other important organ dysfunction
2. Abnormal coagulation function or bleeding tendency
3. History of chronic pain or long-term use of opioid analgesics; Combine patients with

autoimmune diseases and immune dysfunction
4. Combining mental system disorders or having cognitive impairments; Pregnant or lactating women

Date of first enrolment
01/09/2024

Date of final enrolment
01/09/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
Science and Technology Planning Project of Huizhou City, Guangdong Province

Funder(s)

Funder type

Funder Name
Science and Technology Planning Project of Huizhou City, Guangdong Province

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available