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Effects of thoracic epidural anesthesia in patients with acute pancreatitis and early organ failure

Submission date 22/03/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/03/2026	**Overall study status** Ongoing	
Last Edited 24/03/2026	**Condition category** Digestive System	

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

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Study information

Scientific Title
Effects of thoracic epidural anesthesia in patients with acute pancreatitis and early organ failure: a multicenter, open-label, randomized, parallel- controlled trial

Acronym
TEAPAN

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/02/2026, Ethics Committee of Sir Run Run Shaw Hospital (QinChun Road 3#, Hangzhou, 310012, China; +86 0571-86006906; -), ref: 2023-869-04

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Effective interventions to improve organ function and prognosis in patients with acute pancreatitis

Interventions
Randomization was performed using a stratified block design with randomly permuted block sizes, stratified by center, via a computer-generated program. Patients will be randomized to receive thoracic epidural analgesia for at least 5 days and a maximum of 7 days (intervention group) or conventional analgesic treatment (control group).
Patients assigned to the intervention group will receive TEA as soon as possible after randomization. An epidural catheter was placed in an intervertebral space between the eighth and tenth thoracic vertebrae by a certified anesthesiologist. A test dose of 3 mL of 1% lidocaine was administered to assess the anesthetic level and confirm the efficacy and safety of epidural anesthesia. Upon confirmation, 0.15% ropivacaine 250mL + sufentanil 0.3 μg/mL was administered via continuous infusion at 5-7 mL/h. According to clinical analgesic requirements, a bolus of 2-3 mL was added as necessary.
Patients assigned to the control group will receive conventional analgesic treatment. The analgesic treatment was based on the WHO analgesic ladder, including intravenous administration of nonsteroidal anti-inflammatory drugs (e.g., flurbiprofen) and intravenous administration of opioid analgesics (e.g., tramadol).
Pain was assessed every 4 hours on the day of surgery (within 24 hours). From the second day post-surgery until the day of catheter removal, pain was assessed three times daily (every 8 hours). Pain management goals were similar among both groups: an NRS (Numeric Rating Scale) score of ≤3 in communicative patients with intact consciousness, or a CPOT (Critical-Care Pain Observation Tool) score of ≤2 in non-communicative patients.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Organ failure-free days (OFFD) to 14 days of enrolment measured using the number of OFFD, defined as the number of days alive without organ failure. Organ failure is defined on individual SOFA-2 score of 2 or more for cardiovascular, respiratory, or renal organ systems; only the final period of OFFD will be counted, at days 1 to 14 after enrolment. Patients discharged from the

hospital before 14 days will be considered alive and free from organ failure since the day of discharge. Patients who died before day 14 will be assigned zero OFFD.

Key secondary outcome(s))

1. SIRS-free days to 14 days of enrolment measured using the number of days the patient survived without meeting the SIRS diagnostic criteria at days 1 to 14 after enrolment

2. The severity-of-disease measured using the Acute Physiology and Chronic Health Evaluation II (APACHE II) score at days 1, 3, 5, and 7 after enrolment

3. Organ support-free days to 14 days of enrolment measured using the number of days the patient survived without requiring respiratory support, renal replacement therapy, or circulatory support within the 14-day of enrollment at days 1 to 14 after enrolment

4. Assessment of pain in ICU measured using the Numeric Rating Scale (NRS) and Critical-Care Pain Observation Tool (CPOT) scores at days 1, 3, 5, and 7 after enrolment

5. Dosage of analgesics used measured using data collected from records on the dosage of analgesics used at days 1 to 7 after enrolment

6. Subject satisfaction with analgesic treatment measured using a 5-point Likert scale (ratings: not at all satisfied, slightly satisfied, neutral, very satisfied, and extremely satisfied) at days 1 to 5 after enrolment

7. Incidence of Infected Pancreatic Necrosis (IPN) measured using data collected from records on the incidence of IPN at day 28 after enrolment

8. Number of interventional drainage or retroperitoneal pancreatic necrosectomy debridement and drainage procedures required measured using data collected from records on the interventional drainage or retroperitoneal pancreatic necrosectomy debridement and drainage procedures required at day 28 after enrolment

9. Incidence of Deep Vein Thrombosis (DVT) measured using data collected from records on the incidence of DVT at day 28 after enrolment

10. Incidence of sepsis measured using data collected from records on the incidence of sepsis at day 28 after enrolment

11. Incidence of gastrointestinal fistula measured using data collected from records on the incidence of gastrointestinal fistula at day 28 after enrolment

12. Incidence of abdominal bleeding measured using data collected from records on the incidence of abdominal bleeding at day 28 after enrolment

13. Acute pancreatitis severity measured using data collected from records on the CT Severity Index (CTSI) score at day 28 after enrolment

14. Intra-abdominal pressure measured using the intravesical method (bladder pressure measurement) at 3-6 hours after treatment and on days 1, 3, 5, and 7 after enrolment

15. Average caloric/protein intake measured using data collected from records on the average caloric/protein intake at days 1 to 7 after enrolment

16. Tolerance of enteral nutrition measured using data collected from records on the tolerance of enteral nutrition at days 1 to 7 after enrolment

17. GI dysfunction measured using the Gastrointestinal Dysfunction Score (GIDS) at days 1 to 7 after enrolment

18. All-cause mortality measured using data collected from records on all-cause mortality at day 28 after enrolment

19. Intensive Care Unit (ICU) free-days, defined as the number of days alive and discharge from the ICU measured using data collected from records at day 28 after enrolment

20. Total cost of this hospitalization measured using data collected from records at from enrolment to discharge

21. Health-related quality of life measured using European Quality of Life Five-Dimension Five-Level Scale (EQ-5D-5L) at Days 180, 365 after enrolment

22. Symptoms and quality of life measured using PAN-PROMISE score at days 180 and 365 after enrolment

23. Recurrence rate of acute pancreatitis measured using data collected from records on the recurrence rate of acute pancreatitis at day 365 after enrolment

24. Incidence of chronic pancreatitis measured using data collected from records on the incidence of chronic pancreatitis at day 365 after enrolment

25. Incidence of Post-pancreatitis diabetes mellitus measured using data collected from records on the incidence of Post-pancreatitis diabetes mellitus at day 365 after enrolment

26. Incidence of pancreatic exocrine insufficiency measured using data collected from records on the incidence of pancreatic exocrine insufficiency at day 365 after enrolment

Completion date
30/04/2031

Eligibility

Key inclusion criteria
1. Aged between 18 and 70 years
2. Admitted to the hospital within 72 h of the onset of abdominal pain, diagnosed with acute pancreatitis
3. With organ failure as defined by the sequential organ failure assessment-2(SOFA-2)score for respiration, renal and cardiovascular systems
4. Voluntary participation; signed informed consent required

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Pregnant or lactating women, or those planning pregnancy within 6 months
2. Acute pancreatitis associated with chronic pancreatitis or pancreatic neoplasms
3. Patients who have undergone retroperitoneal percutaneous drainage
4. Post-cardiopulmonary resuscitation status with unresolved neurological dysfunction
5. Patients with a history of severe primary cardiovascular, respiratory, renal, hepatic, hematological, malignant tumor, or immune diseases
6. Patients with contraindications to TEA: those who are allergic to local anesthetics; those accompanied by severe systemic infection, infection at the puncture site, epidural abscess, or central nervous system infection; those with central nervous system diseases such as spinal cord lesions, spinal nerve root lesions, or intracranial hypertension; patients in shock; those with anatomical variations or a history of back surgery related to the epidural space, making TEA impossible; those with coagulation disorders or those who have not met the required withdrawal time for anticoagulant or antiplatelet medications; those with mental illness, severe neurosis, or other conditions that make cooperation impossible.
7. Participation in other interventional clinical studies within the past 3 months
8. Other conditions deemed unsuitable for inclusion by the investigator

Date of first enrolment
01/04/2026

Date of final enrolment
01/04/2031

Locations

Countries of recruitment
China

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ROR
https://ror.org/00ka6rp58

Funder(s)

Funder type

Funder Name
Sir Run Run Shaw Hospital

Alternative Name(s)
, SRRSH

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available