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Effect of buccal acupuncture therapy on postoperative gastrointestinal function in patients undergoing colorectal surgery

Submission date
02/09/2024

Recruitment status
No longer recruiting

Registration date
28/09/2024

Overall study status
Ongoing

Last Edited
18/03/2026

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Despite optimized Enhanced Recovery After Surgery (ERAS) protocols, postoperative gastrointestinal dysfunction remains a major clinical challenge for patients undergoing colorectal cancer surgery. This study aims to promote postoperative gastrointestinal function recovery in patients with colorectal cancer through buccal acupuncture therapy to improve the prevention and treatment of postoperative gastrointestinal dysfunction, reduce the incidence of postoperative gastrointestinal dysfunction, promote rapid recovery of patients, and reduce medical costs.

Who can participate?
Patients aged between 18 and 80 years old undergoing elective radical colorectal cancer surgery

What does the study involve?
Patients will be randomly assigned to a buccal acupuncture group and a control group. Patients in the buccal acupuncture group will receive buccal acupuncture treatment 30 minutes before surgery and 30 minutes after awakening, with needles retained for 20 minutes each time. The control group patients will receive conventional treatment without cheek acupuncture intervention. All patients will receive standardized anesthesia management and Enhanced Recovery After Surgery (ERAS) protocols and patient-controlled intravenous postoperative pain management. The primary outcome is to assess the time to first defecation, with secondary outcomes assessing the time to first flatus, the time to first tolerated liquid diet, the time to first tolerated semi-liquid diet, postoperative pain, levels of motilin and gastrin, and quality of life.

What are the possible benefits and risks of participating?
Benefits: The protocol for this clinical study has been reviewed by the Medical Ethics Committee of the participating hospital to maximize the protection of participants' rights and interests and ensure scientific validity. Buccal acupuncture not only helps regulate the qi and blood of the triple energizer, promoting the smooth flow of vital energy in the internal organs to improve gastrointestinal function, but also better controls pain, reduces perioperative stress response,

and decreases the use of general anesthesia and analgesic medications. With its proven effectiveness and absence of toxic side effects, buccal acupuncture is gradually becoming an important complementary strategy for the comprehensive prevention and treatment of postoperative ileus (POI). This procedure has significant advantages, including being safe, painless, and effective, making it a cost-efficient new approach that integrates Traditional Chinese Medicine (TCM) and Western medicine.

Risks: Buccal acupuncture does not cause severe structural damage and has minimal risk of bleeding or hematoma at the puncture site, which can usually be stopped with simple pressure. Researchers will closely monitor participants throughout the study, and in the event of any adverse or serious adverse events, timely measures will be taken to manage the situation appropriately.

Where is the study run from?
Changzhou First People's Hospital

When is the study starting and how long is it expected to run for?
June 2024 to June 2027

Who is funding the study?
Applied Basic Research Project of Changzhou Science and Technology Bureau

Who is the main contact?
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Scientific

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Additional identifiers

Protocol serial number
Applied Basic Research Project of Changzhou Science and Technology Bureau (CJ20220098)

Study information

Scientific Title
A randomized controlled trial to evaluate the efficacy of buccal acupuncture in the recovery of gastrointestinal function after colorectal cancer surgery

Acronym
BAR-GIC Trial

Study objectives
Buccal acupuncture therapy under the Enhanced Recovery After Surgery (ERAS) pathway can further accelerate the recovery of gastrointestinal function in patients undergoing laparoscopic colorectal cancer surgery

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/06/2024, Changzhou First People's Hospital Ethics Committee (185 Guqian Street, Tianning District, Changzhou City, Jiangsu Province, 213000, China; +86 519 6887 0965; czyyirb@163.com), ref: (2024) Teaching No. 029

Study design
Single-center single-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Prevention, Safety, Treatment

Health condition(s) or problem(s) studied
Prevention and treatment of postoperative gastrointestinal dysfunction in patients with colorectal cancer

Interventions
This study is a randomized, single-blind, controlled trial involving patients undergoing elective radical colorectal cancer surgery. Participants will be randomly assigned to either the buccal acupuncture group or the control group. Randomisation will be conducted using a computer-generated random number table to ensure allocation concealment. All patients will receive standardized anesthesia and Enhanced Recovery After Surgery (ERAS) management strategies. The buccal acupuncture group will receive cheek acupuncture treatment 30 minutes before surgery and 30 minutes after awakening, with needles retained for 20 minutes each time. The control group will receive conventional treatment. Postoperative analgesia will be provided with patient-controlled intravenous analgesia (PCIA) in both groups. The study aims to explore the effectiveness and safety of buccal acupuncture therapy in promoting the recovery of gastrointestinal function in patients after colorectal cancer surgery.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Time to first defecation measured using patient self-report from the end of surgery to the first occurrence of bowel movement

Key secondary outcome(s))
1. Time to first flatus measured using patient self-report from the end of surgery to the first passage of gas
2. Time to first tolerate a liquid diet measured using patient self-report from the end of surgery to the first successful intake of a liquid diet without gastrointestinal intolerance
3. Time to first tolerate a semi-liquid diet, measured using patient self-report from the end of surgery to the first successful intake of a semi-liquid diet without gastrointestinal intolerance
4. Postoperative ileus measured using the I-FEED score on postoperative day 4
5. Postoperative pain score measured using the Visual Analog Scale (VAS) at 30 minutes after awakening, 24 hours postoperatively, and 48 hours postoperatively
6. Motilin and gastrin levels measured using the enzyme-linked immunosorbent assay (ELISA) at 30 minutes before surgery, 30 minutes after awakening, and 24 hours postoperatively
7. Quality of life measured using the EORTC QLG Core Questionnaire (EORTC QLQ-C30) at baseline and 30 days postoperatively

Completion date
01/06/2027

Eligibility

Key inclusion criteria
1. Age 18-80 years old, no gender restrictions
2. Body mass index (BMI) ≤40 kg/m2

3. American College of Anesthesiologists (ASA) grade I to III
4. Radical resection of colorectal cancer should be performed at the selected time

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
94

Key exclusion criteria
1. Long-term use of opioids, psychotropic drugs, non-steroidal drugs, etc
2. A history of alcoholism and/or mental illness
3. Tumor recurrence
4. There is an infection in the cheek, or the coagulation function is abnormal
5. Have trigeminal neuralgia or facial paralysis
6. An enterostomy is required

Date of first enrolment
06/06/2024

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
China

Study participating centre
Changzhou First People's Hospital
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Sponsor information

Organisation
Changzhou Science and Technology Bureau

ROR
https://ror.org/00wgk5w17

Funder(s)

Funder type
Government

Funder Name
Changzhou Municipal Science and Technology Bureau

Alternative Name(s)
, CZST

Funding Body Type
Government organisation

Funding Body Subtype
Local 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?
Abstract results			18/03/2026	No	No
Basic results		18/03/2026	18/03/2026	No	No

Statistical Analysis Plan	18/03/2026	18/03/2026	No	No