

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

Submission date 02/09/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/09/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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?
Mrs Yang Ping, yp364394838@163.com

Contact information

Type(s)
Scientific

Contact name
Mrs Ping Yang

Contact details
168 Honghe Road, Xinbei District
Changzhou City, Jiangsu Province
China
213000
86+ 13861247672
yp364394838@163.com

Type(s)
Principal Investigator

Contact name
Dr Lan Qiu

Contact details
The First People's Hospital of Changzhou, 185 Guqian Street, Tianning District
Changzhou City, Jiangsu Province
China

213000
+86 13915089989
qiulanmz@163.com

Type(s)

Public

Contact name

Mr Jiang Shen

Contact details

The First People's Hospital of Changzhou, 185 Guqian Street, Tianning District
Changzhou City, Jiangsu Province
China
213000
86+ 13806123631
2251594829@qq.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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; cyyirb@163.com), ref: (2024) Teaching No. 029

Study design

Single-center single-blind randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital, Medical and other records

Study type(s)

Prevention, Treatment, Safety, Efficacy

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

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 measure

Time to first defecation measured using patient self-report from the end of surgery to the first occurrence of bowel movement

Secondary outcome measures

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 QLQ Core Questionnaire (EORTC QLQ-C30) at baseline and 30 days postoperatively

Overall study start date

01/06/2024

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

Age group

Mixed

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

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**

185 Guqian Street, Tianning District

Changzhou City, Jiangsu Province

China

213000

Sponsor information

Organisation

Changzhou Science and Technology Bureau

Sponsor details

185 Juqian Street, Tianning District

Changzhou City, Jiangsu Province

China

213000

86+ 0519 68870312

yykjk80814@163.com

Sponsor type

Government

Website

<http://www.czfph.com/>

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

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

01/07/2027

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