

Clinical application of acupuncture in the treatment of low anterior resection syndrome after rectal cancer surgery

Submission date 12/08/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/08/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/05/2023	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Low anterior resection syndrome (LARS) is a collection of symptoms that people who have undergone a partial or total resection of the rectum might have. These symptoms include, for example, faecal incontinence or leakage, frequency or urgency of stools, loose stools, incomplete bowel movement, or tenesmus.

Through the patient-reported symptom scale and anorectal pressure test, the effectiveness of acupuncture in the treatment of low anterior resection syndrome for rectal cancer will be preliminarily evaluated, the details of the electroacupuncture intervention plan will be determined, and the onset time will be clarified.

This study will explore the feasibility of acupuncture treatment of low anterior resection syndrome for rectal cancer, and the attitudes, experiences, feelings and acceptance of different patients.

Who can participate?

Patients 18-75 years old who have undergone a partial or total resection of the rectum for cancer treatment.

What does the study involve?

Acupuncture at Baliao point 3 times a week for 4 weeks, a total of 12 times. In addition to acupuncture at Baliao point, the acupoints can be selected according to the patient's syndrome differentiation. For example, Shangjuxu and Xiajuxu will be selected for participants who have received radiotherapy. Also, Baihui and Changqiang will be selected for those who have had diarrhea for a long time.

After completing at least 4 weeks of treatment, 20 patients who are willing to cooperate with the interviews will be selected for semi-structured qualitative interviews.

What are the possible benefits and risks of participating?

Benefit: The patients will receive electroacupuncture treatment and routine blood and urine routine, liver and kidney function, anorectal pressure (needed by some patients) examination for free, and a 300 yuan transportation subsidy will be given to the subjects after completing the

trial. It can improve the symptoms of low anterior resection syndrome to some extent, including improvement in unpredictable bowel function, emptying difficulties, altered stool consistency, urgency, increased stool frequency, incontinence, and repeated painful stool soiling. Potential risks: needle breakage after acupuncture, fainting, local skin infection, bleeding, hematoma, other systemic discomfort after acupuncture, etc.

Where is the study run from?

Third Affiliated Hospital of Beijing University of Chinese Medicine (China)

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

March 2022 to June 2025

Who is funding the study?

Beijing Municipal Health Commission (China)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CFH2022-4-7046

Study information

Scientific Title

Clinical application of acupuncture in the treatment of low anterior resection syndrome after rectal cancer: an exploratory mixed methods research

Acronym

AFLARS

Study objectives

To preliminarily evaluate the efficacy and the feasibility of acupuncture in the treatment of low anterior resection syndrome (LARS) for rectal cancer, and try to find a more convenient and effective treatment for LARS.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/07/2022, IRB of the Third Hospital Affiliated to Beijing University of Chinese Medicine (no. 51, Xiaoguan Street, Andingmenwai, Chaoyang District, Beijing, 100029, China; no telephone number provided; zydsyec@126.com), ref: BZYSY-2022KYKTPJ-07

Study design

Mixed methods research including interventional single-arm clinical trial and semi-structured interviews

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bowel function

Interventions

Current interventions, as of 09/05/2023:

This study is a mixed method study that includes an interventional single-arm clinical trial and semi-structured interviews. A 30 minutes electroacupuncture intervention at Baliao acupoints (BL31, BL 32, BL 33, BL 34) will be provided to participants three times per week for 4 weeks.

Semi-structured interviews will be conducted with 20 participants to understand patients' experience and feelings. The follow-up time points are 1, 3, and 6 months after the end of the 4-week treatment period.

Previous interventions:

This study is a mixed method study that includes an interventional single-arm clinical trial and semi-structured interviews. A 30 minutes electroacupuncture intervention at Baliao acupoints (BL31, BL 32, BL 33, BL 34) will be provided to participants two times per week for 8 weeks. The follow-up time points are 1, 3, and 6 months after the end of the 8-week treatment period.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Current primary outcome measure as of 09/05/2023:

Intestinal function is measured using a low anterior resection syndrome (LARS) score at baseline and once a week, 5 times in total.

(Low anterior resection syndrome (LARS) scale: refer to LARS scale, scoring the severity of urgency, frequency, clustering, incontinence for flatus and incontinence for liquid stool, 0-20 is classified as no LARS, 21-29 as mild, and 30-42 as severe)

Previous primary outcome measure:

Intestinal function is measured using a low anterior resection syndrome (LARS) score at baseline and once a week, 9 times in total.

(Low anterior resection syndrome (LARS) scale: refer to LARS scale, scoring the severity of urgency, frequency, clustering, incontinence for flatus and incontinence for liquid stool, 0-20 is classified as no LARS, 21-29 as mild, and 30-42 as severe)

Key secondary outcome(s)

Current secondary outcome measures as of 09/05/2023:

1. Intestinal function is measured using an MSKCC Bowel Function Instrument at baseline, and once a week, 5 times in total
2. Bowel functions are measured using anorectal manometry at baseline and after 12 acupuncture treatments
3. Quality of life is measured using an EQ-5D-5L instrument at baseline and every 2 weeks, 3 times in total
4. Quality of life is measured using an EORTC-QLQ-C30 instrument at baseline and every 4 weeks, twice in total

Previous secondary outcome measures:

1. Intestinal function is measured using an MSKCC Bowel Function Instrument at baseline, and once a week, 9 times in total
2. Bowel functions are measured using anorectal manometry at baseline and after 16 acupuncture treatments
3. Quality of life is measured using an EQ-5D-5L instrument at baseline and every 2 weeks, 5 times in total
4. Quality of life is measured using an EORTC-QLQ-C30 instrument at baseline and every 4 weeks, 3 times in total

Completion date

30/06/2025

Eligibility

Key inclusion criteria

Current inclusion criteria as of 09/05/2023:

Patients who are admitted to the outpatient or inpatient Department of Acupuncture, Moxibustion and Minimally Invasive Oncology, The Third Affiliated Hospital of Beijing University of Traditional Chinese Medicine, meet the following conditions:

1. Age 18-75 years old
2. Meet the LARS diagnostic criteria, and the LARS score is greater than 20
3. KPS score over 60 points, the expected survival time is more than 3 months
4. Have good communication and understanding skills, and be able to independently report outcome indicators and conduct qualitative interviews
5. Agree to participate in this study and sign the informed consent

Previous inclusion criteria:

Patients who are admitted to the Outpatient Department of Acupuncture, Moxibustion and Minimally Invasive Oncology, The Third Affiliated Hospital of Beijing University of Traditional Chinese Medicine, meet the following conditions:

1. Age 18-75 years old
2. Meet the LARS diagnostic criteria, and the LARS score is greater than 20
3. KPS score over 60 points, the expected survival time is more than 3 months
4. Have good communication and understanding skills, and be able to independently report outcome indicators and conduct qualitative interviews
5. Agree to participate in this study and sign the informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

Key exclusion criteria

Current exclusion criteria as of 09/05/2023:

1. Those who have a history of other anorectal surgery or trauma affecting bowel movements in the past; those who have a history of spinal cord, brain, and, other nerve damage, who cannot control defecation; those who have experienced serious complications, allergic reactions, or adverse events during acupuncture treatment in the past, who cannot cooperate or refuse to Those who tolerate acupuncture treatment
2. Patients with other intestinal or anorectal diseases; patients with postoperative complications such as anastomotic leakage, anastomotic bleeding, anastomotic stenosis, and intestinal puncture
3. Those who are receiving other acupuncture treatments
4. Sacral deformity caused by any reason, those who cannot accurately locate the acupoints
5. Patients with serious primary diseases such as cardiovascular, liver, kidney, and hematopoietic system and mental illness;
6. Participating in other clinical investigators

Previous exclusion criteria:

1. Those who have a history of other anorectal surgery or trauma in the past; those who have a history of spinal cord, brain, and, other nerve damage, who cannot control defecation; those who have experienced serious complications, allergic reactions, or adverse events during acupuncture treatment in the past, who cannot cooperate or refuse to Those who tolerate acupuncture treatment
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3. Those who are receiving other acupuncture treatments
4. Sacral deformity caused by any reason, those who cannot accurately locate the acupoints
5. Patients with serious primary diseases such as cardiovascular, liver, kidney, and hematopoietic system and mental illness;
6. Participating in other clinical investigators

Date of first enrolment

10/03/2023

Date of final enrolment

31/12/2024

Locations

Countries of recruitment

China

Study participating centre

Third Affiliated Hospital of Beijing University of Traditional Chinese Medicine

Department of Acupuncture and Moxibustion and Minimally Invasive Oncology

No.51, Andingmen Outer Street

Chaoyang District
Beijing
China
100029

Sponsor information

Organisation

Third Hospital Affiliated to Beijing University of Chinese Medicine

Funder(s)

Funder type

Government

Funder Name

Beijing Municipal Health Commission

Alternative Name(s)

, Beijing Municipal Bureau of Health, Commission municipale de la Santé de Beijing, BMHB

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

China

Results and Publications

Individual participant data (IPD) sharing plan

The participant-level data will not be available as it is not covered in the informed consent for participants. The research data will apply the Research Electronic Data Capture (REDCap) for data collection and management.

IPD sharing plan summary

Not expected to be made available