ISRCTN12537763 https://doi.org/10.1186/ISRCTN12537763

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

Registration date
16/08/2022

Overall study status
Completed

Last Edited
09/05/2023

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
Dr Ming Yang
yangming@bucm.edu.cn

Contact information

Type(s)
Scientific

Contact name
Dr Ming Yang

ORCID ID
http://orcid.org/0000-0002-2954-7435

Contact details
Floor 4,Comprehensive building
No.51, Andingmen Outer Street
Chaoyang District
Beijing
China
100029
+8613671273351
yangming@bucm.edu.cn

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 measure
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)

Secondary outcome measures
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

Overall study start date
10/03/2022

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

Age group

Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
60

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
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

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

Sponsor details
No. 51, Xiaoguan Street
Andingmenwai
Chaoyang District
Beijing
China
100029
+86 10-84980751
zydsyec@126.com

Sponsor type
Hospital/treatment centre

Website
http://wjw.beijing.gov.cn

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

Publication and dissemination plan
Planned publication in a high-impact journal.

Intention to publish date
01/12/2025

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