ISRCTN13146325 https://doi.org/10.1186/ISRCTN13146325

Does electroacupuncture reduce gut problems in patients treated with pain-relieving drugs after keyhole surgery to the lower bowel?

Submission date
13/04/2018

Recruitment status
No longer recruiting

Registration date
10/05/2018

Overall study status
Completed

Last Edited
08/04/2021

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Bowel problems, abdominal pain and wound pain are common after-effects of laparoscopic (keyhole) surgery to the colon or rectum (lower part of the intestine). This can be a result of organs being pulled or squeezed during surgery, blood leakage and/or the use of anesthetics and other drugs. Recovery of normal gut function after abdominal surgery is an important part of the recovery period. Acupuncture has been identified as an effective method for the recovery of intestinal function. This study aims to recruit 160 patients to compare electroacupuncture treatment and conventional (usual) treatment to prevent gut problems after keyhole surgery of the colon and rectum.

Who can participate?
People at the age of 30-80 years old who undergo laparoscopic surgery to the colon or rectum.

What does the study involve?
Participants are randomly allocated to electroacupuncture group and conventional group. In the electroacupuncture group, they take electroacupuncture treatment as well as conventional treatment. In the conventional group, they accept conventional treatment alone.

What are the possible benefits and risks of participating?
All participants receive conventional treatment and the participants in intervention group additionally accept electroacupuncture treatment for free. Information obtained from this research might help patients in the future. By taking part in this study there are no risks of physical injury or harm.

Where is the study run from?
Guang' anmen Hospital and Xiyuan hospital, China Academy of Chinese Medical Sciences

When is the study starting and how long is it expected to run for?
March 2018 to December 2021

Who is funding the study?
The Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences (China)

Who is the main contact?
Dr Mingyue Gao
gmyaaa@126.com

Contact information

Type(s)
Scientific

Contact name
Dr Mingyue Gao

Contact details
16 Nanxiao Street, Dongzhimen, Dongcheng District, Beijing, China
Beijing
China
100700

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
To observe the effect of gastrointestinal dysfunction in electroacupuncture versus conventional treatment for the patients with laparoscopic colorectal surgery

Study objectives
Electroacupuncture and conventional treatments might be superior to individual conventional treatment .

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of the Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences, 18/01/2018, 2017-12-25-1-2

Study design
A prospective, randomized controlled and single blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Gastrointestinal dysfunction and intestinal infection are common symptoms after laparoscopic colorectal surgery, which will affect the operation effect and prolong postoperative recovery time.

Interventions
Intervention arm: Electroacupuncture combined with conventional treatment, which included 80 participants
Control arm: Conventional treatment, which included 80 participants

Electroacupuncture treatment group:
Patients in the electroacupuncture group receive acupuncture with electrostimulation with stainless steel needles and a Hwato SDZ-II electroacupuncture device after surgery. After standard disinfection of the acupoints with 75% ethanol solution, the acupuncturist will position the disposable medical needles (0.30 mm diameter x 1.5 mm length) perpendicular to the skin at the subject's acupoints and then needle them into the skin. Electroacupuncture is given for 30 minutes, once a day, starting 24 hours after surgery and lasting for 7 days. Acupoints are the following, which are known to promote gastrointestinal motility: ST36 (Zusanli), ST37 (Shangjuxu), LI4 (Hegu), LR3 (Taichong). After standard disinfection of the acupoints with 75% ethanol solution, the acupuncturist will position the disposable medical needles (0.30 mm diameter × 1.5 mm length) perpendicular to the skin at the subject's acupoints and then needle them into the skin. Patients in conventional treatment group receive routine intravenous nutrition lasts for the patients discharge from hospital and analgesic pump lasts 3 days after surgery.
Conventional treatment group:
Routine intravenous nutrition lasts for the subjects out of hospital.
The randomisation process:
Patients will be assigned in a 1:1 ratio to either the electroacupuncture group or the conventional group using random numbers generated in EXCEL. The random numbers will be concealed inside sealed, opaque, serialized envelopes and only one assigned investigator can open them. When recruiters identify a subject who meets the criteria for participation, they will obtain a sequence number for that subject from the researcher in charge of the randomization numbers. Statisticians will be unaware of the group assignment.

When the patients have incisional pain/abdominal pain, an analgesic pump will be used. According to the degree of pain and if the VAS score greater than 6 points, they can self-control the button of pump for pain relief. Flurbiprofen axetil Injection is administered intravenously at 50 mg at times when the pain is unbearable after 30 minutes of the analgesic pump being controlled by the patient.

Intervention Type
Procedure/Surgery

Primary outcome measure
Time to first flatus and defecation

Secondary outcome measures
1. VAS score of postoperative incisional pain and abdominal pain 24 h, 2 days and 3 days after surgery
2. Quality of life: We will use the postoperative recovery quality score to evaluate the participants' quality of life.
3. Hospital days

Overall study start date
01/03/2018

Completion date
30/12/2021

Eligibility

Key inclusion criteria
Participant inclusion criteria as of 19/11/2018:
1. Participants must be aged 30–80 years;
2. The evaluation function of elderly mental state scale (MMSE) ≥ 27 points;
3. Colonic and rectal diseases have been diagnosed and colorectal cancer is not diffuse
4. TNM stage is less than stage 3;
5. Participants who have undergone laparoscopy;
6. Participants with colon or rectum disease who have undergone a laparotomy;
7. The ASA level of the American anesthesiologist is I-II;
8. Nutritional risk screening confirmed that NRS 2002 score ≥ 3 points in patients before operation;
9. Participants have signed informed consent.

Previous participant inclusion criteria:
1. Participants must be aged 30–80 years;
2. The evaluation function of elderly mental state scale (MMSE) ≥ 27 points;
3. Colonic and rectal diseases have been diagnosed and colorectal cancer is not diffuse
4. TNM stage is less than stage 3;
5. Participants who have been treated by laparoscopy;
6. The ASA level of the American anesthesiologist is I-II;
7. Nutritional risk screening confirmed that NRS 2002 score ≥ 3 points in patients before operation;
8. Participants have signed informed consent.

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
160

Key exclusion criteria
1. People who take sedatives and antidepressants for a long time;
2. People treated with acupuncture for nearly a month;
3. People with a history of abdominal surgery in the last three months;
4. People with mental disorders or difficulties in language communication can not finish the research;
5. People who can not receive electroacupuncture treatment.

Date of first enrolment
01/04/2018

Date of final enrolment
30/07/2021

Locations

Countries of recruitment
China

Study participating centre
Guang' anmen Hospital, China Academy of Chinese Medical Sciences
China
100053

Study participating centre
Xiyuan Hospital, China Academy of Chinese Medical Sciences;
China
100091

Sponsor information

Organisation
Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences

Sponsor details
16 Nanxiao Street, Dongzhimen, Dongcheng District, Beijing, China
Beijing
China
100700

Sponsor type
Not defined

ROR
https://ror.org/042pgcv68

Funder(s)

Funder type
Not defined

Funder Name
Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences

Results and Publications

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

Intention to publish date
30/04/2022

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request