

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/04/2021	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

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 anaesthetics 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
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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

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

Study type(s)

Treatment

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 x 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(s)

Time to first flatus and defecation

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

All

Sex

All

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request