

The effect of low-frequency electrical stimulation combined with abdominal acupoint massage on postoperative recovery after cesarean section

Submission date 22/05/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/05/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/05/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The study aims to explore how a combination of low-frequency electrical stimulation and abdominal acupoint massage affects the recovery of the digestive system after a cesarean section (a surgical procedure to deliver a baby).

Who can participate?

Adults between the ages of 20 to 40 years who underwent a cesarean section

What does the study involve?

A total of 120 patients who had just had surgery were randomly divided into different groups for a study. One group, the control group (group A, with 30 people), received standard care after their surgery. The other groups, called the observation groups (group B, C, and D, with 30 people in each group), received a special nursing treatment that combined low-frequency electrical stimulation with a massage of specific points on the abdomen. This special treatment started at different times after the surgery: 6-8 hours for group B, 8-10 hours for group C, and 10-12 hours for group D.

What are the possible benefits and risks of participating?

Benefits include a better recovery of gastrointestinal function following cesarean section and the reduction of pain. Risks are minimal and include minor side effects from stimulation .

Where is the study run from?

Wenzhou People's Hospital (China)

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

Who is funding the study?

Wenzhou People's Hospital (China)

Who is the main contact:
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Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Exploring the optimal timing of low-frequency electrical stimulation combined with abdominal acupoint massage for the recovery of gastrointestinal function after cesarean section

Study objectives

Low frequency electrical stimulation combined with abdominal acupoint massage has a good effect on the recovery of gastrointestinal function after cesarean section.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 15/04/2020, The Ethics Committee of Wenzhou People's Hospital (57 Canghou Street, Wenzhou City, Zhejiang Province, Wenzhou, 325099, China; +86 577 8830 6798; zjq1980120@163.com), ref: 2020-260

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied

Prevention of gastrointestinal dysfunction in patients after cesarean section.

Interventions

A total of 120 postoperative patients were randomly assigned to either the control group (group A, n=30) or the observation group (group B, C and D, n=30). The control group received conventional interventions, while the observation group received a nursing intervention consisting of low-frequency electrical stimulation combined with abdominal acupoint massage starting at 6-8 hours (group B), 8-10 hours (group C) and 10-12 hours (group D) after the operation. The primary outcomes included the time to first bowel sound, time to flatus, time to defecation, and time to lactation. The secondary outcomes included postoperative visual analogue scale(VAS) pain scores, the rate and severity of abdominal distension, and serum levels of prolactin (PRL) and vasoactive intestinal peptide (VIP).

Randomisation:

An administrative staff member handled patient enrollment, and patients randomly draw a number card from an opaque envelope prepared in advance, ranging from 1 to 120. Then, based on the random numbers generated by Excel, the patients were automatically assigned patients into 1 of the 4 groups. Patients were allocated into the control group (Group A, n=30), Group B (n=30), Group C (n=30), Group D (n=30) using the 1:1:1:1 ratio. All data were collected post-intervention. All subjects and investigators involved in recruitment, data collection, and statistical analysis were blinded to randomization status throughout the study. Only the operator knew about the interventions the subjects received, but she had no involvement in the study process.

Intervention Type

Behavioural

Primary outcome(s)

Calculated from the end of surgery:

1. Time to first bowel sound
2. Time to first flatus
3. Time to first defecation
4. Time to lactation

Key secondary outcome(s)

1. The postoperative visual analogue scale(VAS) pain score, evaluate the pain at 24, 48, and 72 hours post surgery using Visual Analogue Scale;
2. The rate and severity of abdominal distension, evaluate abdominal distension 48 hours after surgery through consultation; According to different degrees of abdominal distension, it is classified as mild, moderate, and severe. Mild cases may have abdominal distension, but the incision is not painful; Moderate abdominal distension, local swelling and pain of the incision, tolerable; Severe cases may result in abdominal distension and significant incision pain, which is intolerable;
3. The serum levels of prolactin (PRL) and vasoactive intestinal peptide (VIP) measured using blood sample at 48h after surgery by using enzyme linked immunosorbent assay.

Completion date

31/12/2025

Eligibility

Key inclusion criteria

1. American Society of Anesthesiologists physical status I or II
2. Normal singleton pregnancy with at least 37 weeks of gestation
3. Aged 20 - 40 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

20 years

Upper age limit

40 years

Sex

Female

Key exclusion criteria

1. Emergency surgery
2. Previous bowel surgery
3. Chronic digestive disease
4. Diabetes
5. Hypertension
6. Contraindications to low-frequency electrical stimulation, such as skin damage at relevant acupoints, local tumors, and pacemaker installation

Date of first enrolment

01/10/2024

Date of final enrolment

30/09/2025

Locations

Countries of recruitment

China

Study participating centre

Wenzhou People's Hospital

57 Canghou Street, Wenzhou City, Zhejiang Province

Wenzhou

China

325099

Sponsor information

Organisation

The Ethics Committee of Wenzhou People's Hospital

Funder(s)

Funder type

Government

Funder Name

The basic scientific research projects of Wenzhou City (No. Y2021005)

Results and Publications

Individual participant data (IPD) sharing plan

The original data will be directly shared on Baidu Netdisk before December 31, 2025. The Netdisk connection link is: <https://pan.baidu.com/s/1fc1dJxkd1ueMjqXnOwg7rQ> Password: u7a1

IPD sharing plan summary

Stored in publicly available repository