

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

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<b>Registration date</b> 30/05/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 29/05/2024	<b>Condition category</b> 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

### Contact name

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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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes