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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
Recruiting

Registration date
30/05/2024

Overall study status
Ongoing

Last Edited
29/05/2024

Condition category
Pregnancy and Childbirth

[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
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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment, Efficacy

Participant information sheet
No participant information sheet available

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 measure

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

Secondary outcome measures
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.

Overall study start date
01/01/2021

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

Age group
Adult

Lower age limit
20 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
120

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
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Sponsor information

Organisation
The Ethics Committee of Wenzhou People's Hospital

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

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

Results and Publications

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

Intention to publish date
31/12/2026

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