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Use of convenient aerobic exercise and heating compress to improvement of gas pain and upper abdominal pain after surgery

Submission date 30/07/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/07/2021	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/10/2021	**Condition category** Surgery	[X] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
After laparoscopic (keyhole) surgery, the pain is less than the traditional open surgery, and the recovery is faster. However, during laparoscopic surgery, carbon dioxide gas must be used to penetrate the body in order to make the surgical field clearer. As a result, 35% to 80% of patients experience gas pain and discomfort after surgery, causing trouble. If non-medicinal, simple, and easy-to-operate nursing measures can be used to reduce the occurrence of gas pain and discomfort, it will reduce the use of medical costs.

Who can participate?
Women aged 20 years and above who are admitted to the hospital for gynecological laparoscopic surgery

What does the study involve?
Participants are randomly allocated to the experimental or the control group.
Four hours after the operation, the anesthetic had withdrawn, the experimental group began to perform aerobic exercises for 5-10 times of deep breathing, upper extremity expansion exercises, and hot compresses for 30 minutes. The intervention was performed at 4, 6, 12, and 24 hours after the operation.
The control group followed the routine care of the ward.

What are the possible benefits and risks of participating?
Benefits: The intervention may reduce pain after the operation.
Risks: A hot compress is used to improve blood circulation in the shoulder and neck. If burns occur during use, the host of this study will bear all the medical expenses. If you feel uncomfortable during the process, you can ask the host for explanation or assistance at any time.

Where is the study run from?
Chung Shan Medical University Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
December 2020 to April 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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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
Evaluation of the effect of aerobic exercise and hot compress on the improvement of gas pain and upper abdominal pain after laparoscopic surgery

Study objectives

1. Through the interventional measures of aerobic exercise and heating compress, the experimental group has significantly improved gas pain and upper abdominal pain than the control group
2. Through the interventional measures of aerobic exercise and heating compress, the experimental group has improved the quality of postoperative recovery than the control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/12/2020, Institutional Review Board Chung Shan Medical University Hospital (No. 110, Sec.1, Chien-Kuo N. Road, Taichung, Taiwan 402; +886 (0)4-24739595; irb@csh.org.tw), ref: CS1-20189

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Upper abdominal pain after laparoscopic surgery

Interventions
Participants are randomly assigned to the experimental group and control group, four hours after the operation. Randomisation uses a random number table.

The experimental group starts to perform aerobic exercises for 5-10 deep breaths, chest expansion exercises and hot compresses for 30 minutes each time. The intervention time is as follows: Four times at 4, 6, 12, and 24 hours after operation.

The control group followed the routine care of the ward.

Intervention Type
Behavioural

Primary outcome(s)
Pain is measured used a visual analogue scale at 4 hours and 24 hours after operation

Key secondary outcome(s))
Recovery from surgery is measured QoR-40 questionnaire at 4 hours and 24 hours after operation

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Those gynecological patients who have undergone laparoscopic surgery
2. Adults over 20 years old
3. A clear consciousness can speak, read and understand Mandarin. And those who can fully cooperate
4. Those who accept this experiment and sign the consent form.
5. Those who take general anesthesia
6. If the experimental group and the control group are in the same ward, at least one ward will be separated
7. The attending physician agrees

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
120

Key exclusion criteria
1. Failed laparoscopic surgery was changed to laparotomy
2. Those who have had a shoulder injury
3. BMI value> 30mg/m²
4. Mental patients who are unable to cooperate in the implementation of intervention measures
5. The experimental group and the control group are allocated by random assignment. If the experimental group and the control group are allocated to the same ward, the second income patient will be excluded. Avoid cross-effects and violate research ethics

Date of first enrolment
28/01/2021

Date of final enrolment
29/04/2021

Locations

Countries of recruitment
Taiwan

Study participating centre

Chung Shan Medical University Hospital
No.110, Sec.1
Chien-Kuo N. Road
Taichung
Taiwan
402

Sponsor information

Organisation
Chung Shan Medical University

ROR
https://ror.org/059ryjv25

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Dataset			12/10/2021	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes