ISRCTN18030444 https://doi.org/10.1186/ISRCTN18030444

Acupressure combined with a flexible pressure sensor to treat coughing in patients undergoing bronchoalveolar lavage

Submission date	**Recruitment status**	[_] Prospectively registered
21/10/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/10/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/10/2024	Surgery	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The study focuses on improving the quality of anesthesia recovery in patients undergoing bronchoalveolar lavage (BAL) using flexible bronchoscopy. Traditional recovery methods often involve routine monitoring, but this study explores the potential benefits of combining acupressure with flexible pressure sensor manometry. The primary aim is to investigate whether acupressure, when combined with flexible pressure sensor manometry, can enhance the recovery process post-anesthesia. Specifically, the study examines the impact on postoperative cough frequency, length of stay in the post-anesthesia care unit (PACU), incidence of stress urinary incontinence, and heart rate during the recovery period.

Who can participate?
Adult patients aged 18-64 years old who underwent BALusing flexible bronchoscopy at the First Affiliated Hospital of Zhengzhou University.

What does the study involve?
The patients were randomly divided into two groups: the acupressure group (Group A) and the control group (Group C). After the operation, all patients were transferred to the post-anesthesia care unit (PACU). In Group A, acupressure was applied to specific points (Tiantu [RN22], Chize [LU5], and Taiyuan [LU9]) after the removal of the laryngeal mask. The pressure and duration of the acupressure were measured using flexible pressure sensors. In contrast, Group C received routine PACU monitoring without acupressure.

During the recovery period in the PACU, several parameters were observed and analyzed, including:
Postoperative cough frequency (number of coughs)
Length of stay in PACU
Occurrence of stress urinary incontinence
Heart rate (HR)
These observations aimed to assess the effectiveness of acupressure combined with flexible pressure sensor manometry in improving the quality of anesthesia recovery.

What are the possible benefits and risks of participating?
Benefits: Reduces postoperative cough;Painless treatment of cough
Risks: Local skin redness phenomenon

Where is the study run from?
Department of Anesthesiology and Perioperative Medicine, First Affiliated Hospital of Zhengzhou University, China.

When is the study starting and how long is it expected to run for?
November 2023 to May 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Lijun Jia, fccjialj@zzu.edu.cn

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
Effect of acupressure combined with flexible pressure sensor manometry on the quality of anesthesia recovery in patients undergoing bronchoalveolar lavage-A randomized controlled trial

Acronym
BAL

Study objectives
Acupressure combined with flexible pressure sensor manometry improves the quality of anesthesia recovery

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/12/2023, Research and Clinical Trial Ethics Committee of the First Affiliated Hospital of Zhengzhou University (First Affiliated Hospital of Zhengzhou University, Zhengzhou, 450052, China; +86 13783593652; 13783593652@163.com), ref: 2023-KY-0912-003

Study design
Single-center interventional single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, University/medical school/dental school, Workplace

Study type(s)
Prevention, Treatment, Safety, Efficacy

Participant information sheet

Health condition(s) or problem(s) studied
Acupressure combined with flexible pressure sensor manometry to improve the quality of anesthesia recovery

Interventions
This study is a two-group parallel randomized trial. All the patients were divided into two groups (1:1): the acupressure group (group A) and the control group (group C) using the random number table method.

Group A acupressure method: The patient was asked to inhale, with the thumb acupoint pressed for 2.0s to reach the peak, and the pressure gradually decreased (0~3.5s), and each acupoint was pressed for 3 min. All three acupoints were pressed using the same method. The total

intervention time was 30 min. The pressure of acupuncture points (N) was observed and the time of acupoint pressure was recorded (s).
Group C was not given acupressure after surgery, and the rest of the post-anesthesia care unit (PACU) care was the same as group A's.

Follow-up for both study arms:
During the recovery period of anesthesia:
PACU dwell time; Mean cough during the recovery period from anesthesia (times/min); Mean pulse during anesthesia recovery (times/min); Mild Cough; Severe cough; HR (>100 times/min); BP (>140mmHg); Stress Urinary Incontinence (Female)

After 6 hours:
Cough with bloody sputum; the throat is swollen and sore

Intervention Type
Procedure/Surgery

Primary outcome measure
Cough Grading: The intensity and duration of coughing were recorded. According to the outbreak phase of the cough, a series of coughs in each time course is recorded as 1 cough, and the intensity of the cough is divided into three levels:
mild (1~2 times/min),
moderate (3~4 times/min),
and severe (>5 times/min).
The evaluation was done immediately after extubation, 30 minutes after removal of the laryngeal mask, and on the transfer out of the PACU.

Secondary outcome measures
The following secondary outcome measures data were collected throughout the procedure:
1. Duration of anesthesia
2. Remifentanil dosage
3. Micuronium chloride dose
4. Betamethasone dose
5. Duration of surgery
6. Endotracheal lavage
7. Endotracheal lavage recovery fluid

Overall study start date
01/11/2023

Completion date
30/05/2024

Eligibility

Key inclusion criteria
1. Age between 18-64 years old
2. ASA Class I or II
3. No cough or mild cough

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
Both

Target number of participants
163

Total final enrolment
132

Key exclusion criteria
1. Skin lesions around Tiantu (RN22), Chize (LU5), and Taiyuan (LU9) points
2. Recent massive hemoptysis
3. Diffuse alveolar hemorrhage
4. Untreated active tuberculosis
5. Obvious electrolyte imbalance
6. Inability to understand communication-related trials or informed consent

Date of first enrolment
26/12/2023

Date of final enrolment
30/05/2024

Locations

Countries of recruitment
China

Study participating centre
Department of Anesthesiology and Perioperative Medicine
First Affiliated Hospital of Zhengzhou University
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Sponsor information

Organisation
First Affiliated Hospital of Zhengzhou University

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Sponsor type
Hospital/treatment centre

Website
http://fcc.zzu.edu.cn/

ROR
https://ror.org/056swr059

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
First Affiliated Hospital of Zhengzhou University

Alternative Name(s)
The First Affiliated Hospital of Zhengzhou University,

Funding Body Type
Government organisation

Funding Body Subtype
Other non-profit organizations

Location
China

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal; BMC Anesthesiology

Intention to publish date
25/10/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Lijun Jia, fccjialj@zzu.edu.cn, after publication.

IPD sharing plan summary
Stored in publicly available repository, Available on request, Published as a supplement to the results publication