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Using ultrasound to determine the position of the gap between ribs during surgery

Submission date
12/03/2019

Recruitment status
No longer recruiting

Registration date
06/04/2019

Overall study status
Completed

Last Edited
26/05/2020

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Incorrect intercostal space positioning can cause inconvenience to surgeons, increasing surgery time and even increasing risk. The accuracy of the surgeon's manual positioning depends on the doctor's rich clinical experience and is also influenced by factors such as the patient's gender and body mass index. Determining the intercostal gap by ultrasound guidance is more intuitive. The focus of this double-blind randomized study was to assess the temporal accuracy of ultrasound in the positioning of the intercostal space and compare it to manual positioning.

Who can participate?
Anesthesiologists and surgeons.

What does the study involve?
The temporal accuracy of ultrasound in the positioning of the intercostal space and compare it to manual positioning.

What are the possible benefits and risks of participating?
There are no benefits or risks of participating.

Where is the study run from?
Henan Provincial People's Hospital.

When is the study starting and how long is it expected to run for?
December 2018 to October 2019.

Who is funding the study?
Wei Zhang, who works at Henan Provincial People's Hospital.

Who is the main contact?
Chenxi Li
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Study website

N/A

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2100043

Study information

Scientific Title
The accuracy and efficiency of positioning of the intercostal space under ultrasound guidance compared with manual positioning: an observational study

Study objectives
Compared with manual positioning, the ultrasound-guided rib gap is more accurate and faster.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Observational

Primary study design
Observational

Secondary study design
N/A

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied
Locating the intercostal space during surgery

Interventions
The anesthesiologist and the surgeon participated in the experiment. The surgeon uses the technique to locate the intercostal space and the anesthesiologist uses ultrasound to locate the intercostal space and record the time. After the operation started, after the thoracoscope entered the chest cavity, it is judged whether the positioning of the rib gap was correct by direct vision. There is no follow-up.

Intervention Type
Other

Primary outcome measure
The accuracy of manual positioning and ultrasonic positioning of the rib gap is measured using the number of people positioned correctly divided by the total number of people.

Secondary outcome measures
Total time of manual positioning and ultrasonic positioning of the intercostal space.

Overall study start date
01/12/2018

Completion date
01/10/2019

Eligibility

Key inclusion criteria
1. Undergoing thoracoscopic lung surgery
2. Aged 18 years or older

Participant type(s)
Patient

Age group
All

Lower age limit
18 Years

Sex
Both

Target number of participants
70

Key exclusion criteria
1. Undergoing thoracoscopic single-hole operation
2. Subcutaneous emphysema
3. Rib fractures

Date of first enrolment
01/06/2019

Date of final enrolment
01/10/2019

Locations

Countries of recruitment
China

Study participating centre
Henan Provincial People's Hospital
China
450000

Sponsor information

Organisation
Henan Provincial People's Hospital

Sponsor details
Jinshui District, Zhengzhou City, Henan Province, China
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03f72zw41

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Henan Provincial People's Hospital

Results and Publications

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

Intention to publish date
31/08/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/05/2020	26/05/2020	Yes	No