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Assessment of the vertebral space for the insertion of a needle to inject the drug for spinal anesthesia: a volunteer-based study to assess the ability of the anesthetist to identify the space correctly

Submission date
14/03/2024

Recruitment status
No longer recruiting

Registration date
18/03/2024

Overall study status
Completed

Last Edited
18/03/2024

Condition category
Other

[ ] 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 intervertebral space (between two adjacent vertebrae in the spine) is estimated before performing spinal and epidural anaesthesia using the palpatory method (using hands). Ultrasound accurately identifies the desired intervertebral spaces, hence avoiding the wrong level of injection and avoiding damage to the spinal cord. The aim of this study is to compare the assessment of intervertebral level by palpation and ultrasound.

Who can participate?
Healthy volunteers aged 18 years and over and anaesthetists with various levels of experience

What does the study involve?
Anaesthetists with various levels of expertise will be asked to palpate the patient's back and to mark the space desired, and the chosen level will be noted. An ultrasound machine will be used by a trained researcher and the correlation between the landmark-estimated space and the ultrasound findings will be noted. Participants' factors such as age, gender, BMI, and the presence of vertebral malformations (e.g. scoliosis) will be noted.

What are the possible benefits and risks of participating?
Possible benefits include the correct estimation of intervertebral spaces. There are no expected risks.

Where is the study run from?
King Hamad University Hospital (Bahrain)

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

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Surendranath Venkatesan, surendranath.venkatesan@khuh.org.bh

Contact information

Type(s)
Public, Scientific, Principal investigator

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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
A study to evaluate the correlation between anatomical landmark ultrasound imaging estimation of intervertebral level

Study objectives
Palpation of intervertebral levels may not correctly estimate intervertebral spaces, especially when patients with specific characteristics, such as increased BMI, sclerosed interspinous ligaments and vertebral malformation such as scoliosis, where palpation of the iliac crests and vertebral spinous processes can be difficult. Whereas with ultrasound imaging, the actual

intervertebral spaces can be visualized giving a more accurate estimation. Volunteers were recruited to allow anaesthetists to palpate the space manually and it was correlated by ultrasound estimation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/03/2023, Institutional Review Board - King Hamad University Hospital (Building 2435, Road 2835 Block 228, PO Box 24343, Busaiteen, 228, Bahrain; +973 (0)17444444; khuh@khuh.org.bh), ref: 23-598

Study design
Observational

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Assessment of intervertebral space

Interventions
Verbal consent will be taken from the volunteer participants. Anaesthetists with various levels of expertise will be asked to palpate the patient's back and to mark the space desired, the chosen level will be noted. An ultrasound machine will be used by a trained researcher and the correlation between the landmark-estimated space and the ultrasound findings will be noted. Participants' factors such as age, gender, BMI, and the presence of vertebral malformations (e.g. scoliosis) will be noted.

Intervention Type
Other

Primary outcome(s)
The correlation between anatomical palpation method of intervertebral space estimation and ultrasound estimation. The intervertebral space identified by participants on the two volunteers by the palpatory method was correlated with the ultrasound estimation of the intervertebral space. The difference or agreement between the two different methods was noted. Measured at a single timepoint.

Key secondary outcome(s))
Measured at a single timepoint:
1. The time taken to estimate by anatomical palpation by participants on volunteers and ultrasound estimation by a trained researcher. A timer was kept as a standard and time from beginning to completion of estimation of the intervertebral space was noted in seconds.
2. The effect of experience on correct estimation, noted from personal interviews with the participants.

Completion date

31/03/2024

Eligibility

Key inclusion criteria
1. Willing volunteer
2. Adult volunteer (over 18 years of age)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. Age <18 years
2. Pregnant women
3. Back deformities

Date of first enrolment
01/04/2023

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
Bahrain

Study participating centre
King Hamad University Hospital
Building 2435, Road 2835
Block 228, PO Box 24343

Busaiteen
Bahrain
228

Sponsor information

Organisation
King Hamad University Hospital

ROR
https://ror.org/0538fxe03

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Datasets generated during and/or analysed during the current study will be available upon request from Dr Surendranath Venkatesan (surendranath.venkatesan@khuh.org.bh).
The type of data that will be shared: participants' level of experience, time taken to estimate by palpatory method and ultrasound method and volunteers' age, sex, weight and height will be shared.
Dates of availability: From the last day of completion of study.
Data is anonymised and numbered and the personal identities of both volunteers and participants are concealed.

IPD sharing plan summary
Available on request