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Ideal needle size and location for needle insertion to relieve a condition called tension pneumothorax, which can cause difficulty breathing. A study in an elite rugby team

Submission date 08/03/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/04/2023	**Overall study status** Completed	
Last Edited 04/04/2023	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims

Tension pneumothorax is a very rare event, but a medical emergency. It can happen if there is damage to the lung causing a leak. Air can escape from the lung, into the space between the chest wall and outside of the lung. If air continues to accumulate from the lung in this space, it can compress the lung and the heart. This can then significantly compromise heart and lung function. If this happens out of hospital, a small needle with surrounding tubing (a cannula) can be inserted into the space between the chest wall and lung. The needle is then withdrawn, leaving the tubing which can relieve this tension, and allow better functioning of the heart and lung and allow transfer to hospital.

Previous guidance unanimously recommended carrying out the cannula insertion procedure near the top of the chest. However, research is really mixed as to the best place, and now some guidance suggests carrying out the procedure to the side of the chest. These recommendations are for the general population. There is also a discrepancy of the optimal cannula length to use.

Professional rugby players are very likely to have increased muscle bulk over the chest wall, which previous research has shown. The study aims to take measurements of the chest wall thickness, which may help future guidance on recommendations of the best place to carry out this (very unlikely) procedure.

We are also interested in seeing if there is any correlation between the size of the chest and upper arm and chest wall thickness, which may help identify players where a longer needle may be needed.

The final measurement we will take is the distance from the skin to important structures such as the heart, again to help look at risks by using different approaches and helping research cannula length.

Who can participate?
Professional rugby (union) players aged over 18 years

What does the study involve?
Measurements of the chest wall thickness (with an ultrasound scan), the size of the chest and upper arm and chest wall thickness (with a tape measure), and distance from the skin to important structures such as the heart (using ultrasound).

What are the possible benefits and risks of participating?
Benefit of contributing to research that may save lives.
No risks.

Where is the study run from?
Jersey Sports Medicine and Shockwave Clinic (Jersey)

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

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr David Howell

Contact information

Type(s)
Principal investigator

Contact name
Dr David Howell

ORCID ID
https://orcid.org/0009-0006-7927-3432

Contact details
Jersey Sports Medicine and Shockwave Clinic
Health Plus
Queens Road
St Helier
Jersey
JE2 4HY
+44 7797821932
dave@jerseysportsmedicine.je

Additional identifiers

Study information

Scientific Title

Optimal size and needle position for needle decompression in tension pneumothorax: Observational study in an elite rugby team

Acronym
OSANP

Study objectives
Professional rugby union player size has continued to increase over an 8-year period, which may lead to an increase in failure of needle decompression (NT), in either the 2nd intercostal space, mid clavicular line(2ICS), or 4th/5th intercostal space, just anterior to either the mid axillary or anterior axillary line, (4/5ICS) using a standard 45mm catheter.

In an athletic population, pectoral muscle mass will likely be increased in the 2ICS leading to increased chest wall thickness. There is a risk of failure of NT in tension pneumothorax, and the 4 /5ICS is the preferred initial management.

There is correlation between chest circumference or upper arm circumference and CWT in elite rugby players and this could help identify players in the team that may have an increased CWT and where a longer catheter should be considered.

Replacing the 14G catheter with a longer, purposely made catheters for all, will increase iatrogenic risk.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, Health and Community Services, Jersey, Research Ethics Committee

Primary study design
Observational

Study design
Prospective observational study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Optimal position for needle decompression in tension pneumothorax and assessment of iatrogenic risk in a male professional rugby team.

Interventions
We will use ultrasound to take measurements from the skin to pleural line in the 2nd intercostal space, mid clavicular line, and 4/5th intercostal space, just anterior to the anterior axillary line and just anterior to mid axillary line, along with measurements from here to the pericardium in expiration, and systolic phase of the cardiac cycle. Also, we will take measurements of upper arm and chest circumference to see if there is any correlation with chest wall thickness (CWT).

Ultrasound examination will then take place with the patient lying supine on an examination couch, with the arms relaxed by the side. This will be done using a GE loqiq E ultrasound

machine, using an 8-12Mhz probe in the appropriate setting for the depth. Gel stand-off will be used to capture images, to ensure there is no compression of the chest wall. Images will be captured, and recorded for review, and measurements taken from the skin to the pleural line and entered an excel file.
A cardiology consultant, highly experienced in imaging will also take measurements from the skin to the pericardium, after capturing an image in the systolic phase in the lateral chest positions. This measurement will be performed in expiration, as this is likely to give the best echo windows and shortest distance (therefore greatest iatrogenic risk). However, there may be some variability depending upon echo windows. In some cases, we might also need to reposition the player into a left lateral position rather than prone to obtain good echo window and measurement.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ultrasound

Primary outcome(s)
Chest wall thickness measured by ultrasound between the 2ICS MCL, and 4/5 ICS AAL, and 5ICS MCL at a single time point

Key secondary outcome(s)
Measured at a single time point:
1. Upper arm circumference and chest circumference (with tape measure)
2. Potential of iatrogenic risk (measured with ultrasound from the skin to the pericardium)

Completion date
01/06/2023

Eligibility

Key inclusion criteria
1. Adult players (aged >18 years)
2. Part of a professional rugby team
3. Male

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 Years

Sex
Male

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/05/2023

Date of final enrolment
02/05/2023

Locations

Countries of recruitment
Jersey

Study participating centre
Jersey Reds Rugby Club
La Rue des Landes St Peter's
Jersey
Jersey
JE3 7BG

Sponsor information

Organisation
The Allan Lab

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 available upon request from Dr David Howell - dave@jerseysportsmedicine.je

IPD sharing plan summary

Available on request