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The use of an ambulatory device in treatment of pneumothoraces caused by underlying lung disease

Submission date
24/10/2016

Recruitment status
No longer recruiting

Registration date
24/10/2016

Overall study status
Completed

Last Edited
06/07/2021

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
A pneumothorax is a collection of air around the lung within the chest which can be due to an injury puncturing the lung or due to a leak of air from the lung. A leak of air from the lung can occur spontaneously in patients who have no lung disease (primary spontaneous pneumothorax) or in patients who have lung disease (secondary spontaneous pneumothorax). This causes the lung to collapse, leading to breathlessness and often chest pain. The treatment of a pneumothorax often involves a tube being inserted into the space around the lung to allow the air to escape and the lung to inflate again. The tube inserted in the space around the lung is usually connected to an 'underwater seal' with the tip of the tube left in a bottle of sterile water. This allows air to escape from the chest by bubbling through the water, whilst stopping it from being drawn back into the chest through the tube. This set up means that patients have to carry around a bottle of water with them and can sometimes lead to patients not being as mobile as they could be. Another device which can be used to allow air to escape from the lung but not to re-enter is a Heimlich valve, which is an enclosed plastic valve connected to a chest tube. Studies have shown that Heimlich valves can be useful for the treatment of pneumothorax and may allow patients to be treated at home. For patients with lung disease and secondary spontaneous pneumothorax there are studies suggesting that these valves are safe and have some advantages, but there are no studies directly comparing them against a normal underwater seal. The aim of this study is to find out whether there are any advantages or disadvantages of Heimlich valves compared with underwater seals in patients with secondary spontaneous pneumothorax.

Who can participate?
Patients aged over 18 with secondary spontaneous pneumothorax who require a chest drain

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive usual treatment with an underwater seal. This involves having a chest tubes (drains) placed into the space around the deflated lung, which are connected to an underwater seal drainage system. Those in the second group are treated using a Heimlich valve. This involves having a chest tube

placed into the space around the lung with a one-way valve to stop air coming into the chest through the tube when the patient breathes in. The tube and valve may be attached to a plastic bag to collect fluid. Patients in both groups are followed up for 26 weeks. The study looks at how long patients are in hospital for and will also look at patients' quality of life, the amount of chest pain and breathlessness they have, how many other procedures they might require for treatment of their pneumothorax and when these other procedures are required, and how many go on to require surgery for their pneumothorax or are readmitted to hospital. The study also assesses whether this treatment affects pneumothorax happening again, or any problems related to the procedures.

What are the possible benefits and risks of participating?
It is hoped that all patients will benefit from the lung re-expanding whether it is with a standard chest drain or with a Heimlich valve. There are a few risks with both procedures, such as introducing infection or causing bleeding, but it is not known which treatment is safer or more effective. Both treatments will involve a stay in hospital. Chest X-rays are used for the investigation and monitoring of pneumothorax and will be required whether or not patients take part in the study. The study requires patients to have three chest X-rays, two of which are additional to standard care, one at each of the follow-up visits. There is a small theoretical risk with this extra radiation, but chest x-rays are associated with a low level of radiation. Three X-rays are equivalent to two weeks of background radiation in the UK.

Where is the study run from?
Southmead Hospital and five other NHS hospitals in England (UK)

When is the study starting and how long is it expected to run for?
January 2016 to April 2019

Who is funding the study?
Rocket Medical PLD (UK)

Who is the main contact?
Dr Steven Walker
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
31533

Study information

Scientific Title
Heimlich valves in secondary spontaneous pneumothorax: Enhancing Care (Hi-SPEC)

Study objectives
The aim of this study is to evaluate the effect of Heimlich valves on length of stay in patients admitted to hospital with secondary spontaneous pneumothorax.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West - Exeter Research Ethics Committee, 14/03/2016, ref: 16/SW/0023

Study design
Randomised; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Pneumothorax

Interventions

Patients are randomised to treatment with either a seldinger chest drain or to treatment with a Rocket Pleural Vent in a 1:1 ratio through a randomisation server in random permuted blocks.

Control group: Participants receive treatment with a seldinger chest drain and underwater seal. The procedure for seldinger insertion involves:
1. Positioning the patient comfortably in a semi-recumbent postiion
2. Preparing the sterile area and equipment
3. Cleaning insertion site, using drapes to maintain sterility
4. Administering appropriate and adequate local anaesthetic to insertion site: subcutaneously with orange needle then infiltrating to the pleura with green needle (if required) until air is aspirated
5. Making a small (4-5mm) incision in the skin using the scalpel
6. Inserting the introducer needle until air aspirated
7. Threading the guide wire through introducer needle
8. Removing the introducer needle, leaving guide wire in place
9. Dilating the tract with the dilator thread over the guide wire
10. Feeding the chest drain (12-14g) over the guide wire and removing the wire
11. Connecting the 3-way tap to end of drain in the "off" position
12. Suturing the drain in place and placing an adhesive dressing ("drainfix" or equivalent)
13. Having the assistant prepare the chest drain bottle with 500ml of sterile water (filled to "prefill" line)
14. Inserting connection tubing to chest drain bottle and passing the sterile end to sterile operator to connect to chest drain
15. Opening the 3-way tap and checking flow of air (“bubbling and swinging” through chest drain bottle)

Intervention group: Participants receive treatment with a Rocket Pleural Vent. The procedure for pleural vent insertion includes:
1. Positioning the patient comfortably in a semi-recumbent postiion
2. Preparing the sterile area and equipment
3. Cleaning insertion site, using drapes to maintain sterility
4. Administering appropriate and adequate local anaesthetic to insertion site: subcutaneously with orange needle then infiltrating to the pleura with green needle (if required) until air is aspirated
5. Making a small (4-5mm) incision in the skin using the scalpel
6. Removing the protection sheath from the catheter and slowly inserting the device needle through the skin incision over the superior border of the rib into the pleural space
7. Attaching the syringe and aspirating air to confirm position
8. Once position is confirmed, removing the needle and syringe from the one-way valve by rotating the connection cap anti-clockwise, slowly advancing the catheter into the pleural space whilst removing the needle (leaving only the pigtail catheter in the chest)
9. Once needle is fully removed, securing the catheter to the skin surface using the attached dressings
10. Attaching the valve cap

Following insertion of a Rocket Pleural Vent or a standard chest drain, patients’ care will proceed according to standard care guided by the treating clinician. Decisions regarding removal of the chest drains or Pleural Vent will be made by the treating clinician in reference to BTS guidance and standard local practice. Chest drains or Pleural Vents should be removed at the earliest opportunity following clarifying the absence of an ongoing air leak.

VAS scores for pain and breathlessness will be collected on a daily basis for 4 weeks after randomisation and quality of life data will be collected on a daily basis for the first 14 days after randomisation. Participants will be asked to attend a week 4 and week 12 visit. At this visit they will have a clinical assessment, asked to complete a quality of life questionnaire and have a chest x-ray performed. At week 12 they will also have spirometry. At week 26 they will receive a telephone call asking if they have had recurrence of their pneumothorax.

Intervention Type
Other

Primary outcome measure
Length of hospital admission is measured in days by medical record review at the 4 and 12 week visit.

Secondary outcome measures
1. Breathlessness is assessed using a visual analogue scale (VAS) daily over the first 28 days after randomisation
2. Chest pain is assessed using a visual analogue scale (VAS) daily over the first 28 days after randomisation
3. Quality of life measured using the EQ-5D-5L questionnaire daily over first 14 days after randomisation
4. Number of procedures required for management (including pleural aspirations, chest drain insertion, pleurodesis attempts, thoracic surgical intervention) are measured by medical record review at time of patient discharge and medical record review with patient interview at the 4 and 12 visits.
5. Time to drain removal is measured in days from randomisation are measured by medical record review at time of patient discharge and medical record review with patient interview at the 4 and 12 visits
6. Time to further intervention is measured by in days from randomisation are measured by medical record review at time of patient discharge and medical record review with patient interview at the 4 and 12 visits.
7. Surgical intervention for pneumothorax is measured in days from randomisation are measured by medical record review at time of patient discharge and medical record review with patient interview at the 4 and 12 visits and 26 weeks phone call.
8. Adverse event rate is measured by patient interview and medical record review at the 4 and 12 visits and 26 weeks phone call.
9. Recurrent pneumothorax is assessed by recording the occurrence of ipsilateral recurrent pneumothorax at end of 26 weeks follow up by patient interview and medical record review

Overall study start date
01/09/2015

Completion date
01/12/2019

Eligibility

Key inclusion criteria
1. New diagnosis of a secondary spontaneous pneumothorax as confirmed by a chest radiograph or CT scan

2. Secondary spontaneous pneumothorax defined by known underlying lung disease or a patient > 50 years old with a significant smoking history (>20 pack years)
3. Chest drain insertion indicated for treatment of pneumothorax according to current BTS guidelines
4. Chest drain insertion possible at both 2nd intercostal space

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 66; UK Sample Size: 66

Total final enrolment
41

Key exclusion criteria
1. Current iatrogenic or traumatic pneumothorax
2. Drain already in place for pneumothorax
3. Previous history of tension pneumothorax
4. Features of tension pneumothorax associated with current presentation
5. Evidence of hydropneumothorax or haemopneumothorax
6. Age <18 years
7. Patients bed-bound prior to pneumothorax
8. Contraindication to either chest drain insertion or rocket pleural vent insertion
9. Females who are pregnant or lactating
10. Patients with no access to a telephone
11. Inability to comply with trial requirements or provide informed consent

Date of first enrolment
01/11/2016

Date of final enrolment
01/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Southmead Hospital
Dorian Way
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
John Radcliffe Hospital
Headley Way
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OX3 9DU

Study participating centre
North Staffordshire Royal Infirmary
Princes Road
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ST4 7LN

Study participating centre
Musgrove Park Infirmary
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TA1 5DA

Study participating centre
Great Western Hospital
Marlborough Road
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Study participating centre
Guy's Hospital
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SE1 9RT

Sponsor information

Organisation
North Bristol NHS Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Industry

Funder Name
Rocket Medical PLC

Results and Publications

Publication and dissemination plan
Both the trial protocol and trial results will be published in a peer reviewed journal.

Intention to publish date
01/12/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are available from Dr Emma Keenan (Emma.Keenan@nbt.nhs.uk) on reasonable request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/06/2021	06/07/2021	Yes	No
HRA research summary			28/06/2023	No	No