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Randomised ambulatory management of primary pneumothorax (RAMPP)

Submission date 05/08/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/08/2015	**Overall study status** Completed	
Last Edited 12/09/2023	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Pneumothorax - air in the pleural space, or more widely known as a collapsed lung - is common (~3,000 patients per year in the UK). The term primary spontaneous pneumothorax (PSP) is used to describe those cases that occur in the absence of trauma, in patients with no underlying established lung disease. Not all patients need to have treatment; such patients are just closely observed until the condition improves on its own. However, many patients will need treatment to re-inflate the lung. In some cases aspiration (removal) of air from the pleural space using cannula and syringe will be enough, but many will need to have a chest drain inserted with standard underwater seal. The average hospital in-patient stay for people having this treatment is 6-8 days. Portable 'ambulatory' devices (such as the Rocket Pleural Vent) provide the option to treat these patients as an outpatient while their lung reinflates. This study compares ambulatory to standard (in-patient treatment with aspiration/chest drain) management of primary pneumothorax.

Who can participate?
Participants aged between 16 and 55 with a PSP.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 undergo ambulatory management of their PSP. Those in group 2 undergo standard (in-patient treatment with aspiration/chest drain) management of their PSP. Primary outcome is total hospital stay up for up to 30 days. The study also investigates whether digitally measured air leak can predict short term outcome (prolonged air leak and requirement for surgery) and whether radiological evidence (on CT scanning) of emphysema-like change and inflammation (swelling of the lung) can predict long term outcome (recurrence rates at 12 months). Patients are assessed at the start of the study with blood tests taken and are reviewed daily either on the ward (standard management group) or as an outpatient (ambulatory group) with chest x-ray, air leak measurement and assessment of breathlessness and chest discomfort. Patients who do not require treatment, will be invited to participate in the observational part of the study and after their initial assessment will be discharged but return for follow up. All patients are followed-up at 1 week post treatment completion (including a CT scan at 2 weeks post completion of treatment), and then at 1, 6 & 12 months after the start of the study.

What are the possible benefits and risks of participating?
One potential benefit of taking part in the study is that those randomly assigned to portable device have the opportunity to be discharged with the device in place. Any procedure on the chest carries some risk. Most patients having a chest drain do not have any problems. However, occasionally patients may experience pain, bleeding or infection at the site of the drain. This risk is the same whether they are in the trial of not. If a patient is enrolled after already having had a chest drain, they may require an extra procedure if they are randomised to the ambulatory device. Patients have at least 6 chest x-rays during their participation in this study, although 4 of these would need to be done whether they were in the study or not. They will also have a CT scan (for research). There are theoretical health risks from excessive radiation exposure, but chest x-rays are the safest tests (the radiation dose is only equivalent to around four days' worth of normal background radiation) and the CT scan will be the lowest possible dose (equivalent of one year's worth of normal background radiation).

Where is the study run from?
University of Oxford, Churchill Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2015 to December 2018

Who is funding the study?
Medical Research Council and the National Institute for Health Research (UK)

Who is the main contact?
Miss Magda Laskawiec-Szkonter

Contact information

Type(s)
Scientific

Contact name
Miss Magda Laskawiec-Szkonter

Contact details
University of Oxford
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19214

Study information

Scientific Title
Ambulatory management of primary pneumothorax: a randomised controlled trial

Acronym
RAMPP

Study objectives
This study compares ambulatory to standard (in-patient treatment with aspiration/chest drain) management of primary pneumothorax.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford A, 19/05/2015, ref: 15/SC/0240

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
1. Ambulatory Device, Rocket Pleural vent insertion
2. Standard Treatment, Aspiration +/- chest drain

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
To assess whether use of an ambulatory device (Rocket Pleural Vent) and treatment strategy reduces hospital stay. Total length of stay in hospital up to 30 days post randomisation. Up to 30 days post randomisation.

Secondary outcome measures
1. Determine whether digitally measured air leak and its evolution over treatment, can predict short term clinical trajectory in patients with pneumothorax, including requirement for prolonged drainage and need for thoracic surgical intervention
1.1. Digitally measured air leak (using Thopaz device), from day 0 (immediately post intervention) to day 4 (or until the chest drain/device removal)
1.2. Rate of surgical referral/failure of medical therapy, on day 4
1.3. Number of pleural procedures required during primary admission, from primary admission until completion of treatment
1.4. Rate of lung re-expansion by comparing the percentage of the hemithorax occupied by the pneumothorax using a CXR scoring system, daily until completion of treatment
2. Establish whether radiological evidence (on CT scanning) of emphysema-like changes (ELC) and inflammation, and serum markers of inflammation can predict long term outcome. Measured at 1 week post completion of treatment and 1, 6 and 12 months post enrolment assessed at follow-up clinic.
2.1.CT evidence of ELC and inflammation: number and size of bullae at apices, and bronchial wall thickness in lung apices (surrogate for inflammation), measured at 1 week post completion of treatment and 1, 6 and 12 months post enrolment assessed at follow-up clinic.
2.2. Correlation with recurrence rate (and time to recurrence) assessed at follow-up clinic
2.3. Serum highly sensitive C-reactive protein (CRP) level on blood test. Measured at baseline.
3. Assess whether ambulatory care and early discharge is safe and cost-effective in the treatment of PSP.
3.1. Rate of complications: intervention site bleeding or infection, blockage of device and need for additional procedure. Measured from initial admission until 1 week post completion of treatment.
3.2. NHS-related healthcare costs by including use of equipment and devices, consumables, medications, and staff and theatre, initial and subsequent hospitalisations over the 12 month follow-up, and outpatient contacts.
3.3. Incremental cost per QALY gained when ambulatory care is compared to standard care, measured from initial admission throughout follow-up.
4. Determine whether patient experience is improved with an ambulatory device (Rocket Pleural Vent): pain of procedure, breathlessness, quality of life assessments (EQ-5D-5L), and time to return to working status.
4.1. Patient related factors: procedural pain/discomfort and breathlessness on VAS scoring system, analgesia usage, and generic health-related and disease-specific quality of life as measured using the Euroqol 5 dimensions 5 levels (EQ-5D-5L). Measured from initial admission throughout follow-up.
4.2. Time to return to work and total days off work, measured from initial admission throughout follow-up.
5. Assess recurrence rate of pneumothorax. Radiological evidence (CXR and or CT) of recurrence.

Measured at 1 week post completion of treatment and at 1, 6 and 12 months post enrolment assessed at follow-up clinic.

Overall study start date
28/09/2014

Completion date
31/03/2020

Eligibility

Key inclusion criteria
1. Presenting with primary spontaneous pneumothorax as confirmed by a chest radiograph or a CT scan
2. Age >= 16 years old and <= 55 years old
3. Ability to consent to participation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
286

Total final enrolment
236

Key exclusion criteria
1. Known or suspected underlying lung disease (including >20 pack year smoking history)
2. Evidence of tension pneumothorax (these patients should be treated immediately as medical emergencies).
3. Females who are pregnant or lactating
4. Inability to consent or comply with the trial requirements
5. Contraindication to thoracic procedure. (Only applies to patients being enrolled into Intervention or Control arms – i.e. not observational cohort)
6. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial

Date of first enrolment
27/08/2015

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Churchill Hospital
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Sponsor information

Organisation
CTRG (University of Oxford)

Sponsor details
Joint Research Office
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of this research will be submitted to the international meetings of respiratory medicine (American Thoracic Society, European Respiratory Society and British Thoracic Society meetings) in abstract form on completion of initial results, with final submission for publication in a high impact respiratory or general medical journal. The findings of this study would be expected to be included in the national treatment guidelines for management of primary pneumothorax on their next iterations. Dissemination of results would in parallel occur through websites and national bodies such as the British Thoracic Society and British Lung Foundation, once the results of the study had been peer reviewed and accepted for publication. We are planning to submit about 6 months after the completion of the study.

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/07/2020	06/07/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Cost-effectiveness	17/08/2022	12/09/2023	Yes	No
Protocol article		11/04/2019	12/09/2023	Yes	No