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Novel evaluations of patients with Primary Pneumothorax using xenon enhanced MRI scan and advanced lung function tests.

Submission date
22/01/2018

Recruitment status
No longer recruiting

Registration date
15/08/2018

Overall study status
Completed

Last Edited
03/03/2021

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
This study looks into why some people have a pneumothorax (collapsed lung). The study will comprise of two parts. The study includes Magnetic Resonance Imaging (MRI) scanning with Xenon enhancement to determine the initial association between Xe-129 lung MRI findings and recurrence rates for primary spontaneous pneumothorax. It also includes breathing tests to determine whether lung function testing and a novel laser gas analyser can identify abnormalities in patients with PSP. This study will recruit people already enrolled into the RAMPP (Randomised Ambulatory Management of Primary Pneumothorax) study in Oxford. We will ask around 20 patients enrolled in Oxford with spontaneous pneumothorax to participate after completion of their treatment for pneumothorax

Who can participate?
Adults aged 18 and older who are enrolled in the RAMPP study.

What does the study involve?
On completion of treatment for their pneumothorax, eligible participants are approached about the study and consented. Ideally within the first 3 months post removal of chest drain, participants are asked to attend for Xenon-129 MRI scan (an MRI scan during which patients will be breathing in Xenon gas) and Lung Function Test: standard and using the Laser Gas Analyser. The Laser Gas Analyser study consists of a 30 min period when the patient breathes either through a facemask or through a mouthpiece while wearing a noseclip. The mouthpiece is connected to the gas analyser. The patient initially breathes air (baseline) and then for the middle ten minutes breathes 100% oxygen (N2 washout period) and back to air again. Following the MRI scanning participants will receive a telephone consultation to check if they have experienced any adverse reactions 24 hours after the scan. If they have, participants will be contacted at a further 24 hours, and then weekly to ensure resolution. The patients will be followed up for 12 months as standard (as part of RAMPP study) and for an additional 12 months as part of OX-RAMPP only (24 months in total). At 24 months, patients will be assessed again to assess evolution of abnormalities over time and long-term recurrence rates.

What are the possible benefits and risks of participating?
This study may lead to better diagnosis and treatments for patients with pneumothorax. As the study is not designed to change current patients' treatment, it is unlikely that they will benefit directly from taking part. Xenon and MRI imaging have been used separately in medicine for many years and we do not expect this procedure to be risky. Patients will be carefully monitored throughout the procedure under the supervision of a doctor. Breathing xenon during magnetic resonance imaging is a relatively new test, though both xenon and magnetic resonance imaging have been used separately for other purposes for many years. Sometimes scans of the lungs can show up a shadow or 'nodule' that was not known about before. If this happened, we would discuss the finding with patients, and would ensure that they had the best medical care to look into and treat this.There will be no radiation risk from the tests. The laser system used for measuring the levels of oxygen and carbon dioxide uses a low power system and the light is entirely enclosed within the device and is therefore harmless. Patients will be expected to wear the activity monitor for ~23hrs per day for three weeks which may be inconvenient. However, the monitor is the size of a watch and should not be too bothersome.

Where is the study run from?
1. Churchill Hospital (UK)
2. Royal Berkshire Hospital (Patient Identification Centre only) (UK)

When is the study starting and how long is it expected to run for?
January 2017 to February 2019

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Miss Magda Laskawiec-Szkonter (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
33404

Study information

Scientific Title
Oxford Sub-study of Randomised Ambulatory Management of Primary Pneumothorax

Acronym
OX-RAMPP

Study objectives
This study aims to look at differences in lungs of patients with primary spontaneous pneumothorax (PSP) using hyperpolarised xenon gas MRI and advanced lung function testing. The Xenon MRI provides more detailed images of the lungs and how they function (ventilation within the lungs). This will be performed for the first time in the context of PSP and correlated with clinical outcomes and recurrence rates. An in-development laser gas analyser will be used to determine lung ventilation to volume ratio in patients with primary spontaneous pneumothorax.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford A Research Ethics Committee, 19/09/2016, ref: 16/SC/0412

Study design
Observational; Design type: Validation of outcome measures

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Respiratory disorders, Primary sub-specialty: Respiratory disorders; UKCRC code/ Disease: Respiratory/ Other diseases of pleura

Interventions
Ideally within the first 3 months post removal of chest drain, patients will be asked to attend for Xe-129 MRI scan and Lung Function Test: standard and using the Laser Gas Analyser. Xe-129 lung MRI requires breathing in hyperpolarized xenon, Xe-129.

The Standard Lung Function and Laser Gas Analyser testing will take place 1-3 months post-completion of treatment (dependent upon the availability of the gas analyser). Standard Lung

Function and Laser Gas Analyser testing will occur in the Lung Function Laboratory at the Churchill Hospital, Oxford. They can be performed before or after the Hyperpolarized Xe-129 MR imaging, ideally on the same day.

Standard lung function testing will performed on all patients, as per NHS Trust and national guidelines ideally prior to the Laser Gas Analyser testing. This will include:
1. Spirometry: FEV1 (Forced Expiratory Volume in 1 second), FVC (Forced Vital Capacity), FEV1 /FVC ratio, and PEFR (Peak Expiratory Flow Rate).
2. Body plethysmography: TLC (Total Lung Capacity), Vital capacity (VC), Functional residual capacity (FRC) and RV (Residual Volume)
3. Diffusion capacity : DLCO (Diffusing Capacity for carbon monoxide), VA (Alveolar Volume), kCO (DLCO/VA diffusing capacity corrected for alveolar volume)

These parameters will allow assessment of any previously undiagnosed obstructive or restrictive defect, and any abnormality of oxygen transfer.

The Laser Gas Analyser study will consist of a 30 min period when the patient breathes either through a facemask or through a mouthpiece while wearing a noseclip. The mouthpiece will be connected to the gas analyser. The patient initially breathes air (baseline) and then for the middle ten minutes breathes 100% oxygen (N2 washout period) and back to air again.

Post-Xe-MRI scan - Safety observation and Follow-up
The participant will receive a telephone consultation to review AE/SAE 24 hours after the scan. If there are any outstanding/non-resolved AE/SAE, the participant will be contacted at a further 24 hours, and then weekly to ensure resolution. The patients will be followed up for 12 months as standard (as part of RAMPP study) and for an additional 12 months as part of OX-RAMPP only (24 months in total). At 24 months, patients will be assessed again to assess evolution of abnormalities over time and long-term recurrence rates.
There is no need for any special safety observation period following the Lung Function and Laser Gas Analyser assessment.

Intervention Type
Other

Primary outcome(s)
Co-primary outcome measures:
1. Comparison of hyperpolarized Xe-129 MRI ventilation and diffusion-weighted maps i.e. percentage ventilation volumes (%VV) and ADC values (cm2/s) with findings from normal control patients (data collected from previous Xe MRI study) and correlation with recurrence rates at 12 months follow-up (in RAMPP study)
2. Ventilation/Volume abnormalities in PSP in comparison with standard lung function and with normal controls (from previous laser gas analyser study)

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
28/02/2019

Eligibility

Key inclusion criteria
1. Recruited into RAMPP study through the Oxford or Reading centre (both interventional and observational cohort patients)
2. Participant is willing and able to give informed consent for participation in the study
3. Female participants of child bearing potential must agree to take appropriate steps to avoid pregnancy in the three months following the hyperpolarized xenon lung MRI scan
4. Male or female, aged 16-55

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Inability to consent or comply with the trial requirements.
2. Inability to lie flat for procedures.
3. Contraindication to MRI examination (e.g. indwelling pacemaker, non-MRI compatible metallic implant, severe claustrophobia, intra-ocular foreign body).
4. Female participants who are pregnant, lactating or planning pregnancy during the course of the study.
5. 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 study, or may influence the result of the trial, or the participant's ability to participate in the study.
6. Epilepsy requiring on-going medical treatment, or a seizure within the past year.

Date of first enrolment
08/02/2017

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Churchill Hospital
Old Road
Headington

Oxford
United Kingdom
OX3 7LE

Study participating centre
Royal Berkshire Hospital (Patient Identification Centre only)
Craven Road
Reading
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RG1 5AN

Sponsor information

Organisation
University of Oxford

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

Results and Publications

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?
Basic results		03/03/2020	03/03/2021	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes