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Upright MRI in lung disease

Submission date
10/05/2018

Recruitment status
No longer recruiting

Registration date
23/05/2018

Overall study status
Completed

Last Edited
10/05/2021

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
The diaphragm is the main muscle helping breathing. This study aims to check the use of MRI in patients with diaphragmatic weakness and patients with COPD (emphysema and chronic bronchitis) who have hyperinflation. In some patients with COPD, air gets trapped in the lungs and causes them to expand too much; this is called hyperinflation. These patients report severe breathlessness, which may be in part because of their diaphragm. It is known that posture affects lung function and breathing and this study will check the effect of posture on the diaphragm. Currently, lung function tests and CT or ultrasound scan are the main tests that are used to check how the diaphragm works. Recently, at University of Nottingham, an imaging approach has been developed using an upright MRI to test patients in a lying position and seated /standing in the same scanner. This may help to test the diaphragm position and shape more accurately and check the effects of posture on the diaphragm. This may help researchers to better understand the relationship between postural changes in diaphragm position and shape and symptoms.

Who can participate?
Healthy volunteers, patients with diaphragmatic weakness and patients with COPD whose lungs are over-expanded

What does the study involve?
Participants are asked to attend the imaging centre only once, where they are scanned at the same visit, which is expected to take 2 hours to complete. They are scanned on two scanners: lying and seated/standing in the new upright scanner and lying in a conventional scanner. The change in diaphragm position and shape caused by a change in posture is assessed, along with impairment in diaphragm movement in COPD patients with hyperinflation.

What are the possible benefits and risks of participating?
Participants will not benefit directly, but the results may help with the use of this test for people who have lung problems. This may give doctors new options for monitoring lung function in these groups of people. The test is not invasive, and there should be no long-term side effects. The scanner does not involve x-rays so does not carry the same risks as CT scans or chest x-rays. MRI uses radio waves similar to those used in radio and TV transmissions. These have a much lower energy than x-rays and as such are considered safe. Strict national safety guidelines are followed, which are designed to prevent the possible hazards of MRI, which are burns and

electric shocks. While there is no evidence to suggest that MRI is harmful during pregnancy, it is not advised to scan pregnant women at fields above 2.5T (2.5 Tesla). The magnets we use are 0.5 T and either 1.5T or 3T scanners. All premenopausal female participants are asked to give a urine sample to test for pregnancy at the study visit before scanning. Another risk of having an MRI scan may be the feeling of claustrophobia so patients who have claustrophobia should not take part in this study.

Where is the study run from?
The study takes place at the clinical research MRI centre at Nottingham Medical School, which is next to Queen's Medical Centre

When is the study starting and how long is it expected to run for?
March 2018 to April 2020

Who is funding the study?
University of Nottingham (UK)

Who is the main contact?
Dr Shahideh Safavi

Contact information

Type(s)
Scientific

Contact name
Dr Shahideh Safavi

Contact details
Respiratory Medicine Office
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.0

Study information

Scientific Title

Upright magnetic resonance imaging in COPD and diaphragm disease

Study objectives
To assess the role of MRI in diagnosing and assessing severity of abnormalities in diaphragm morphology and position in patients with diaphragmatic weakness and patients with COPD with hyperinflation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Wales Research Ethics Committee 6, 15/05/2018, ref: 18/WA/0148
2. HRA and Health and Care Research Wales (HCRW), 16/05/2018, IRAS project ID 243925

Study design
Proof-of-concept clinical trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Diaphragmatic weakness or COPD (chronic obstructive pulmonary disease) with hyperinflation

Interventions
All participants (healthy individuals and patients) will undergo the following tests/procedures:
1. Relevant Past Medical History Including medication history & smoking status.
2. St George's Respiratory Questionnaire
3. MRC Dyspnoea score
4. MRI safety questionnaire
5. Height and weight measurement
6. Vital signs measurement (respiratory rate, oxygen saturations, heart rate, blood pressure)
7. Spirometry
8. Urine pregnancy test for premenopausal women
9. MRI scan using the open upright MRI scanner and a conventional 1.5T or 3T MRI scanner

MRI scan procedure
MRI scan of thorax (including the lungs and diaphragm) will be performed on the Paramed 0.5T MRI scanner and the 1.5T or 3T scanners, located in the SPMIC-QMC. The participant will be

imaged in lying and seating/standing positions. For each posture, they will be scanned after full inspiration and also after full expiration.

Following completion of scanning, to assess the impact on posture on perception of breathlessness, participants will be asked to fill a visual analogue scale for breathlessness for scanning in horizontal and vertical positions.

No contrast agents will be administered to the participant. They will be contacted by phone 24 hours later to monitor wellbeing.

Intervention Type
Other

Primary outcome measure
1. Change in diaphragm position and morphology caused by a change in posture (vertical to horizontal position or vice versa), measured by analysis of MR images once during the one scan visit. Analysis is performed using Matlab software
2. Degree of impairment in diaphragm movement in COPD patients with hyperinflation, measured once during the one scan visit. Analysis is performed using Matlab software. Patient scans are compared to healthy volunteer scans
3. Correlation between lung function abnormality with abnormalities in diaphragm movement as noted on MRI. Spirometry and scan are performed on the same day during the scan visit

Secondary outcome measures
Tolerability data on the ability of participants of each group to adhere to the protocol thus informing the study design of future trials. Participants are asked to fill a visual analogue scale for breathless comparing the severity of breathless in lying and seated positions, right after completing the scans

Overall study start date
01/03/2018

Completion date
30/04/2020

Eligibility

Key inclusion criteria
Healthy volunteers and patients with diaphragm weakness (due to neuromuscular disease, e.g. motor neuron disease, and non-neuromuscular disease e.g. trauma) and patient with COPD with hyperinflation

General inclusion criteria:
1. Adult - male or female, aged 18 to 90 years old
2. Capacity to give informed consent
3. Able to hold their breath for 10 seconds
4. Able to understand the requirements of the study and to cooperate with the study procedures

Cohort-specific inclusion criteria:

Healthy participants:
1. No reported or diagnosed chronic respiratory disease

COPD with hyperinflation:
1. Evidence of airflow obstruction on spirometry – FEV1/FVC < 0.7 and FEV1 <80%
2. Diagnosis of hyperinflation based on imaging or lung function measures

Diaphragm weakness due to non-neuromuscular disease:
1. Established diagnosis of diaphragm weakness due to non-neuromuscular disease, e.g. viral illness, trauma

Diaphragm weakness due to neuromuscular disease:
1. Established diagnosis of diaphragm weakness due to neuromuscular disease

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 per cohort (80 in total)

Total final enrolment
31

Key exclusion criteria
1. Unsuitable for MRI scanning (e.g. have metal implants or pacemaker or contraindicated following questionnaire)
2. Deemed unlikely to comply with instructions during imaging
3. Deemed not fit enough to tolerate procedure
4. Deemed unsuitable by clinical investigator for other reasons
5. History of lung volume reduction procedure

Date of first enrolment
01/06/2018

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
United Kingdom
NG7 2RD

Study participating centre
Nottingham University Hospitals NHS Trust
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham

Sponsor details
Research Governance Office
East Atrium Jubilee Conference centre
Jubilee Campus
Wollaton Road
Nottingham
England
United Kingdom
NG8 1BB

Sponsor type
University/education

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Study protocol will be made available to other researchers if they approach the investigators. At present, the trialists do not intend to make it available online. The trialists plan to publish the results in a high-impact peer reviewed journal within a year after overall trial end date. Interim results may also be published. The results will also be presented at regional, national, and international conferences. Part of the results may be used in students' PhD thesis. Participants will not be identified in any publications arising from the research. The data obtained may be published without any identifying information.

Intention to publish date
30/04/2021

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. This is because the patient cohorts are very niche, and even partially anonymised data is at risk of exposing patients' identities, and patients have asked for their data to remain anonymised. The anonymised dataset will be stored on the University of Nottingham's servers securely for seven years. During this time, all precautions will be taken by all those involved to maintain participants' confidentiality, only members of the research team will have access to participants' personal data. This has been clearly stated in the Participant Information Sheet and participants are asked to provide consent to this prior to recruitment.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2020	10/05/2021	Yes	No
HRA research summary			28/06/2023	No	No