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Functional lung MRI for regional treatment monitoring of patients with cystic fibrosis

Submission date	Recruitment status	[ ] Prospectively registered
19/06/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/06/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/06/2017	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cystic fibrosis is an inherited disease in which the lungs and digestive system become clogged with mucus. Magnetic resonance imaging (MRI) is a type of scan that produces detailed images of the inside of the body. The aim of this study is to test lung MRI techniques in patients with cystic fibrosis and to monitor the immediate effects of breathing in hypertonic saline (a strong salt solution) compared with clinical routine lung function tests.

Who can participate?
Patients aged between 12 and 24 with cystic fibrosis

What does the study involve?
All patients undergo an MRI scan, a lung function test, and oxygen measurements. Then they receive a treatment with inhaled hypertonic saline to produce sputum. Within 2 hours after treatment, another MRI scan is performed. After this MRI scan the participants undergo another lung function test and oxygen measurements. Apart from the MRI scan all other tests are part of the routine clinical outpatient visit.

What are the possible benefits and risks of participating?
There is no benefit to the participant. MRI is a clinically established way of obtaining images of organs and tissues without using radiation. The contrast media used to increase contrast in MRI rarely causes allergic reaction. Side effects of inhalation of hypertonic saline are coughing, a sore throat and chest tightness due to an initial irritation of the airways.

Where is the study run from?
Hannover Medical School (Germany)

When is the study starting and how long is it expected to run for?
August 2012 to December 2014

Who is funding the study?
1. Ernst-August Schrader Stipend (Germany)
2. German Center for Lung Research (Germany)

Who is the main contact?
Prof. Jens Vogel-Claussen

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
1725-2013

Study information

Scientific Title
Functional lung MRI for regional treatment monitoring of patients with cystic fibrosis: a case-control study

Study objectives
To evaluate if quantitative functional lung MRI parameters can detect changes in regional lung function two hours after a single hypertonic saline treatment in comparison to spirometry and multiple breath washout.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics board of the Hannover Medical School (Ethikkomission der MHH), 21/02/2013, ref: 1725-2013

Primary study design
Observational

Study design
Case-control study

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied
Cystic fibrosis

Interventions
All patients receive a pre-treatment MRI scan, lung function test, and oxygen saturation measurements during their outpatient day visit. Then they receive a treatment with inhaled hypertonic saline (7%) on the same day according to the SOP 530.00 of the TDV (Therapeutic Diagnostic Network of the Cystic Fibrosis Foundation) to produce induced sputum. Within 2 hours post treatment, a post-treatment MRI scan will be performed. After this MRI scan the patient will receive another lung function test and oxygen saturation measurements on the same day. Apart from the MRI scan all other tests are part of the routine clinical outpatient visit. During each MRI scan 0.03 mmol/kg Dotarem will be administered i.v. for lung perfusion imaging. During each MRI scan the patient will receive 100% oxygen at a flow rate of 15 l/min for about 10 min.

Intervention Type
Other

Primary outcome(s)
Functional lung MRI parameters at baseline and 2h after treatment

Key secondary outcome(s)
No secondary outcome measures

Completion date
10/12/2014

Eligibility

Key inclusion criteria
1. Patients with cystic fibrosis
2. Aged between 12 and 24
3. Patients must be in a clinically stable condition with a confirmed diagnosis of cystic fibrosis
4. The forced expiratory volume in one second (FEV1) must have a minimum volume of >40 percent predicted for age and gender at the pre MRI lung function test

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Pregnant or breastfeeding women
2. Cigarette smokers
3. Patients with hypertonic saline treatment (HST) within the last 7 days
4. Contraindications to MRI or contrast media (allergy to MRI or CT contrast media, GFR< 30 mL /min/1.73 m2)
5. No (patient or parental) consent to participate

Date of first enrolment
21/02/2013

Date of final enrolment
10/12/2014

Locations

Countries of recruitment
Germany

Study participating centre
Hannover Medical School
Hannover
Germany
30625

Sponsor information

Organisation
Hannover Medical School

ROR
https://ror.org/00f2yqf98

Funder(s)

Funder type
Research organisation

Funder Name
Ernst-August Schrader Stipend

Funder Name
German Center for Lung Research

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Jens Vogel-Claussen

IPD sharing plan summary
Available on request