

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

Submission date 19/06/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/06/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/06/2017	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
Prof Jens Vogel-Claussen

Contact details
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30625

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 (Ethikkommission der MHH), 21/02/2013, ref: 1725-2013

Study design

Case-control study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital

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

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 measure

Functional lung MRI parameters at baseline and 2h after treatment

Secondary outcome measures

No secondary outcome measures

Overall study start date

22/08/2012

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

Age group

Mixed

Sex

Both

Target number of participants

20

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

Sponsor details

Department of Diagnostic and Interventional Radiology
Carl-Neuberg-Str. 1
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Germany
30625

Sponsor type

University/education

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**Publication and dissemination plan**

Planned publication in 2017

Intention to publish date

31/12/2017

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