Validation of bi-dimensional (2D) and three-dimensional (3D) Fourier Decomposition (FD) as Magnetic Resonance Imaging (MRI) technique to assess lung ventilation and perfusion compared to computed tomography (CT), Hyperpolarised gases (HP-MRI) and Contrast-Enhanced MRI (CE-MRI)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON55881

Source
ToetsingOnline

Brief title
VIPS MRI

Condition

- Respiratory disorders congenital
- Congenital respiratory tract disorders

Synonym
cystic fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: cystic fibrosis foundation

Intervention

Keyword: cystic fibrosis, lungs

Outcome measures

Primary outcome

• Amount of TA quantified on end-expiratory MR images expressed as % TA over

the total lung volume

• Ventilation defect (VD) on FD-MRI ventilation map expressed as % of total

lung volume,

• Amount of TA quantified on end-expiratory CT images (CF patients only)

expressed as % TA over the total lung volume

• PFT outcomes related to TA (FEF75, FEF25-75, and LCI).

Secondary outcome

Secondary study parameters will be used to assess image quality between the

centres and reliability of the FD-MRI derives outcomes.

• Image quality of each sequence between the centres expressed as:

o SNR

o T1, T2 and geometric distortion (GD) measurements

o Spatial temporal resolution

o Diffusion Weighted Imaging (DWI) measurements

• Image quality on patients with CF and healthy volunteers will be assessed

using a 5 point scale image quality score:

1. excellent image quality

2. mild peripheral airways blurring and motion artifacts

3. moderate peripheral airways blurring and motion artifacts

4. severe moderate peripheral airways blurring and motion artifacts

5. non diagnostic

• Variability assessment for multiple measurements of image quality parameters

on phantoms images between the centres will be tested with ICC

or CCC analysis according data distribution. Also Bland-Altman plots

will be used to assess systematic errors

• Intra and inter-observer variability of semi-quantitative and quantitative

FD-MRI derived parameters will be tested with ICC (or CCC) and

Bland-Altman plots

Study description

Background summary

Novel promising MRI sequences have been developed that are possibly sufficiently sensitive to allow monitoring of structural abnormalities(12). In addition, MRI sequences have been developed that possible allow non-invasive monitoring of perfusion and ventilation(13). Finally, MRI sequences have been developed to detect lung inflammation, which could allow the monitoring of lung inflammation without the need for PET-CT or PET-MRI(14).
However, before these novel MRI sequences can be utilized routinely, to improve our monitoring options for CFLD on a wider scale, they have to be integrated into a patient-friendly time-efficient protocol that can be standardized across centers for the major MRI vendors (GE, Philips, Siemens). In addition, some

further validation of these novel sequences is needed.

In 2014 we formed the ventilation, inflammation, perfusion and structure (VIPS-MRI) consortium with the ambition to jointly develop a VIPS-MRI platform that could be used across MRI vendors. The VIPS-MRI consortium includes the following centers: Erasmus MC (EMC), Rotterdam, Netherlands; Medizinische Hochschule Hannover (MHH), Hannover, Germany; Royal Hallamshire Hospital Sheffield (RHHS), Sheffield, UK and Princess Margaret Hospital (PMH), Perth, Australia.

Study objective

The final goal of this validation plan is to develop an MRI platform that can provide information about ventilation, inflammation, perfusion and structure (VIPS-MRI) in a single MRI examination of 30 minutes for safe and efficient monitoring of CFLD.

Study design

Prospective study on FD-MRI and CT scan

With this amendment, we would like to include other hospitals to perform the standardization of image quality using MRI phantoms and on three healthy volunteers. Because of COVID restrictions, we cannot visit the centers initially included (Hannover, Germany; and Sheffield, UK) in the projects.
To overcome this problem, we will include other hospitals in Netherlands with similar MRI systems in order to perform the analysis on phantoms and 3 volunteers. Regarding the recruitment of volunteers, in light of the COVID-19 crisis and the complexity of the logistic, and to minimize the number of people involved in the study, we aim to volunteer ourselves for the MRI scans: the PI (P Ciet), the MRI physicist (P Wielopolski) and the PhD student (G Colzani).

Finally, a preliminary analysis of the data received from the center of Hannover shows incomplete MRI data. To fulfill this data gap, we would like to add the MRI data from a similar ongoing study in the hospital of Treviso, one of our collaborating centers. The MRI protocol in this hospital is identical to our MRI protocol and they are also using a different MRI system, which is the same of that of Hannover. The study of Treviso has been approved by the local IRB, and an amendment has been submitted to share the data with the Erasmus MC.

Study burden and risks

The burden for the healthy volunteers is minimal. Participation involves one or two MRI-scans with a maximum duration of 60 minutes.
The healthy volunteers are members of the research team and have extensive expertise in performing MRI-scans.

As for the patients in the center of Treviso there are no risks or extra burden associated with participation in this study; they will only be asked to give informed consent for the use of their MRI-scans for the VIPS-MRI study.

The results of this study have the potential to improve clinical understanding and disease management. The new VIPS MRI protocol may improve detection and quantification of structural and functional changes in the CF patients which otherwise would not have been detected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

CF patients
• Diagnosed with CF with sweat and genetic testing
• Age between 10-18 years
• Scheduled for biennial CT scan
• Willing and capable to perform spirometer controlled chest MRI
• Informed consent

Healthy Volunteers
• Age 10-18 years
• Willing and capable to perform spirometer controlled chest MRI
• Informed consent

Healthy volunteers (MRI standardization)
• Age 18 years and older
• Willing and capable to perform chest MRI
• Informed consent

Exclusion criteria

All
• MRI contraindication (i.e. cardiac pacemaker, metallic implant, hearing aids, etc.)
• Claustrophobic
• Pregnancy
• Not willing or unable to perform MRI

CF Patients
• Recent (< 1 month) RTE with use of i.v. antibiotics
• Chronic oxygen therapy
• Any other severe comorbidities that could limit imaging

Healthy volunteers
• Recent (< 1 month) history of lung disease (i.e. pneumonia)
• Known history of chronic lung disease (i.e. asthma)
• Known history of congenital lung disease (i.e. bronchopulmonary dysplasia, tracheomalacia)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-04-2019
Enrollment:	19
Type:	Actual

Ethics review

Approved WMO Date:	30-05-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-08-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-06-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL64041.078.17
Other	NL6618 (NTR6948)