THORACIC FLUID ASSESSMENT BY DYNAMIC CONTRAST-ENHANCED MRI AND BIOIMPEDANCE SPECTROSCOPY: AN EXPLORATIVE STUDY IN HEALTHY SUBJECTS

Published: 31-10-2014
Last updated: 22-04-2024

This study evaluates the normal range dynamic contrast-enhanced MRI bolus kinetic parameters in healthy subjects. The sensitivity of the bolus kinetic parameters to fluid challenges is evaluated. The correlation between change in thoracic impedance...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON40803

Source
ToetsingOnline

Brief title
Extravascular lungwater assessment by CeMR and BIS

Condition

- Heart failures

Synonym
intrathoracic bloodvolume; congestion

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Astron subsidie STW,Medtronic B.V.

Intervention

Keyword: Impedance, Indicator dilution theory, Intrathoracic blood volume

Outcome measures

Primary outcome

A. To optimize the DCE-MRI sequence parameters and to evaluate a reference values for indicator dilution curves derived parameters in healthy volunteers

B. To evaluate whether bolus kinetic derived DCE-MRI parameters can track changes in response to fluid challenge/auto-transfusion in healthy volunteers

C. To evaluate the agreement between changes in bolus kinetic parameters measured by DCE-MRI and changes in impedance measured by bio-impedance spectroscopy

Secondary outcome

A. To evaluate the relationship between bolus kinetic parameters and RV and LV functional parameters.

B. To evaluate reproducibility of MR based bolus kinetic parameters measurement and to evaluate sensitivity to MR sequence parameters.

Study description

Background summary

Heart failure is a major health problem, which is characterized by reduced cardiac function leading to pulmonary congestion. Most episodes of acute heart failure requiring unplanned hospitalization are due to pulmonary congestion.

There is urgent clinical need for quantitative, reproducible and minimally invasive and noninvasive methods to assess thoracic fluid status. The potential value of dynamic contrast-enhanced magnetic resonance imaging (DCE-MRI) to this end has been suggested and demonstrated in vitro, and in this study we now aim to compare intra-thoracic volume assessment by dynamic contrast-enhanced MRI and bioimpedance spectroscopy.

Study objective

This study evaluates the normal range dynamic contrast-enhanced MRI bolus kinetic parameters in healthy subjects. The sensitivity of the bolus kinetic parameters to fluid challenges is evaluated. The correlation between change in thoracic impedance and change in bolus kinetic parameters in response to a fluid challenge is evaluated.

Study design

Prospective nonrandomized pilot study.

Study burden and risks

The whole study will take 3 hours of the volunteer's time. Gadolineum will be injected however the amount will be 10% of the permitted dose.
To reduce the chance of harm, a creatinin clearance will be estimated in advance. The chance on allergic reaction is smaller than 0.1% and in very rare cases nefrogenic systemic fibrosis can be developed. This chance is larger in patients with renal insufficiency and these volunteers are excluded from participating the trial.

Deo et al reported in end-stage renal disease an incidence of 4.3 per 1000 patients for developtment of nephrogenic systemic fibrosis. Todd et al found an increased risk to cutaneous changes of nephgenic systemic fibrosis, odds ratio fo 14.7; 95% CI 1.9-117) compare with patients who were not exposed to gadolineum

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL

Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5623 EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age >18 years
• Informed consent.
• Body mass index between 18 and 25

Exclusion criteria

• end-stage renal or hepatic disease
• pregnancy
• mild or moderate renal insufficiency, (GFR<60 mL/min);
• risk for developing nephrogenic systemic fibrosis;
• general contra-indications to magnetic resonance imaging
• pro-inflammatory state, vascular endothelial dysfunction

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-03-2015
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	31-10-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL50327.060.14