Impact of arterio-venous fistulas on cardiac contractility in hemodialysis patients evaluated using cardiac magnetic resonance derived functional and geometrical parameters

Published: 06-02-2017
Last updated: 14-04-2024

To perform a detailed non-invasive analysis of mechanical activation under different volume loading conditions and to describe the accompanying hemodynamic response.

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

Summary

ID

NL-OMON43002

Source
ToetsingOnline

Brief title
Effect of shunt flow on cardiac contractility in hemodialysis patients

Condition

- Heart failures
- Renal disorders (excl nephropathies)

Synonym
cardiac contractility, cardiac function

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Vakgroep Interne Geneeskunde

Intervention

Keyword: AV shunt, cardiac MRI, contractility, hemodialysis

Outcome measures

Primary outcome

Mechanical activation pattern of the human heart and the accompanying

hemodynamic response.

Secondary outcome

n/a

Study description

Background summary

The pathway of mechanical activation of the human heart is altered by volume overload, as encountered in hemodialysis patients. Assessment and analysis of these alterations have been challenging throughout the years. Recent technological innovations allow non-invasive (in-vivo) mapping of mechanical activation patterns of the human heart. Improved insight in these activation patterns and the associated hemodynamic response may contribute to better medical treatment and optimized follow-up strategies in this patient group.

Study objective

To perform a detailed non-invasive analysis of mechanical activation under different volume loading conditions and to describe the accompanying hemodynamic response.

Study design

Prospective, observational, follow-up study. Study duration has been defined as a maximum of two years follow-up.

Study burden and risks

Although non-invasive, CMR can cause nausea, headache or general discomfort, especially in subjects suffering from claustrophobia.

Contacts

Public
Onze Lieve Vrouwe Gasthuis

Jan Tooropstraat 164
Amsterdam 1061AE
NL
Scientific
Onze Lieve Vrouwe Gasthuis

Jan Tooropstraat 164
Amsterdam 1061AE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients at least 18 years of age.
Patients undergoing hemodialysis.

Exclusion criteria

Unable to give informed consent.
Any contraindication for MRI, e.g. claustrophobia.
Weight > 200 kilo.
Participation in another clinical trial.
Pregnant women, or women of child bearing potential and who are not on a reliable form of birth control.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-01-2017
Enrollment:	45
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-02-2017
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	NL58898.100.16