Clinical Validation of 4D Flow MRI Derived Pressure-Volume Loops

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The purpose of the study is to compare parameters of 4D flow derived non-invasive PV-loop to invasively derived intracardiac pressure recording.

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

Summary

ID

NL-OMON56991

Source
ToetsingOnline

Brief title
4D Flow MRI Derived Pressure-Volume Loops

Condition

- Heart failures

Synonym
Cardiac function, Heart Failure

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Nederlandse Vereniging voor Radiologie (NVvR)

Intervention

Keyword: 4D flow MRI, Cardiac catheterization, Pressure-volume loop

Outcome measures

Primary outcome

Main trial endpoints include maximum pressure, (mmHg), minimum pressure, (mmHg), end-systolic volume, (mL), and end-diastolic volume, (mL). Secondary endpoints include stroke volume, (mL), stroke work, (J), pressure-volume area, (J), ejection fraction, (%), isovolumic relaxation constant (Tau), (ms), end-systolic pressure volume relationship, (mmHg/mL), and end-diastolic pressure volume relationship, (mmHg/mL).

Secondary outcome

Not applicable

Study description

Background summary

Hemodynamic evaluation using pressure-volume (PV) loops is crucial for understanding cardiac function and diagnosing pathology, however it is reliant on invasive catheterization. Promising non-invasive alternatives such as four-dimensional cardiovascular magnetic resonance flow imaging (4D flow MRI) and computational fluid dynamics (CFD) offer comprehensive visualization and analysis of blood flow dynamics. By combining these techniques, it's possible to estimate PV-loops non-invasively, showing promising results and potentially reduce the need for invasive catheterization.

Study objective

The purpose of the study is to compare parameters of 4D flow derived non-invasive PV-loop to invasively derived intracardiac pressure recording.

Study design

A prospective non-randomized single group observational study, where subjects who are scheduled for invasive cardiac catheterization will undergo a pressure recording in the left ventricle, as well as a 4D flow cardiac MRI examination on the same day or within one week before or after the invasive catheterization. During the cardiac catheterization procedure, an additional pressure wire will be introduced in the left ventricle cavity by using an ultrathin, flexible pressure catheter (OptoWire III Pressure Guidewire, Opsens Inc., Québec, Canada). Additionally, patients will also undergo intracardiac 4D flow MRI within one week before or after the invasive procedure. Parameters from the PV-loops between the two methods will be compared to determine the validity of the non-invasive PV-loops.

Study burden and risks

The study includes patients that will already undergo invasive cardiac catheterization. The only additional procedure required, is positioning of the ultrathin pressure catheter through the aortic valve into the left ventricle cavity. This is only associated with a minor risk of arrythmias, which are typically transient. During the procedure the patient is closely monitored. The 4D flow MRI examination does not add any increased risks for the patient given the fact that no gadolinium is used. Both procedures facilitate the potential clinical validation of non-invasive PV-loops, and would benefit the overall population by minimizing the need for invasive cardiac function assessment in the future.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Aged 18 years or older.
Will undergo invasive cardiac catheterization for clinically indicated reasons.
Eligible for undergoing an MRI examination.

Exclusion criteria

Contraindications for undergoing an MRI examination (e.g. non-compatible MR material or devices).
Moderate or severe aortic valve stenosis.
Left ventricle outflow tract obstruction.
Prosthetic aortic valve.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024

Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	CAAS MR Solutions
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-09-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-10-2024
Application type:	Amendment
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	NL86844.100.24