The Connection between Mechanical Alternans measured by Pressure-Volume (PV) Loop catheter in Patients with Ischemic Heart Failure and the Occurrence of Microvolt T wave Alternans (MTWA).

Published: 23-11-2010
Last updated: 03-05-2024

The main objective is to investigate mechanical alternans and MTWA in patients with heart failure caused by coronary artery disease to demonstrate a possible correlation between these two phenomena.

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

Summary

ID

NL-OMON34243

Source
ToetsingOnline

Brief title
MEA trial

Condition

- Heart failures

Synonym
heart failure, reduced heart function

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: AMC/AMR

Intervention

Keyword: heart failure, ischemia, mechanical alternans, MTWA

Outcome measures

Primary outcome

Presence or absence of mechanical alternans and MTWA.

Secondary outcome

Differences in reduced or more preserved LVEF and the occurrence of the two

phenomena

Occurrence of ventricular tachyarrhythmic events

Influence of LV compliance on arrhythmogenesis of the infarction border zone.

Study description

Background summary

In patients with severe heart failure and aortic valve disease mechanical alternans or pulsus alternans (a condition in which there is a beat-to-beat oscillation in the strength of cardiac muscle at a constant heart rate) is observed. The mechanisms linking mechanical to electrophysiological dysfunction in heart failure are still under investigation, but impaired calcium cycling is the most striking abnormality of failing myocytes, and is most responsible for contractile dysfunction. Yet it remains unclear how this influences susceptibility to arrhythmias. The MTWA is suggested as a risk marker to identify high risk patients for potential VTEs but the underlying mechanism is not completely understood. The aim of this study is to investigate this in a clinical setting by measuring LV parameters using a PV loop conductance catheter and generate TWA recording simultaneously to demonstrate a possible correlation between these two phenomena in patients with ischemic heart failure

and find out if MTWA could turn into a more valuable risk stratifier. Our hypothesis is that alternating changes in LV filling explain the electrocardiogenesis of TWA by changing the position of the heart relative to the body surface electrodes in an alternating way.

Study objective

The main objective is to investigate mechanical alternans and MTWA in patients with heart failure caused by coronary artery disease to demonstrate a possible correlation between these two phenomena.

Study design

Observational study

Study burden and risks

Positioning the condunctance catheter requires 30 seconds - 1 minute extra fluoroscopy time. According to the advice of the radiation commitee, this causes minor risk. The high resolution electrodes could cause skin reactions such as irritation and itching. The standard procedure will be extended by 30 minutes maximally.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients will be included if they are over 18 years and under 85 years and able to give informed consent. Patients with heart failure caused by coronary artery disease. LVEF * 35% measured by echocardiogram. Patients with an indication for electrophysiological examination.

Exclusion criteria

hemodynamically instable patients
age under 18 and over 85 years
heart failure not caused by coronary artery disease
severe co-morbidity

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):	01-09-2010

Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL33244.018.10