The multicenter Cardiology Monitoring Platform (mCMP-registry)

Published: 01-07-2021
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To optimize (early) diagnosis and risk-stratification of (early) cardiomyopathy phenotypes and to create a better understanding of underlying pathophysiological processes.

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

Summary

ID

NL-OMON52272

Source
ToetsingOnline

Brief title
mCMP-registry

Condition

- Heart failures

Synonym
cardiovascular disease, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiologie, cardiomyopathy, multicentre, registry

Outcome measures

Primary outcome

This is a prospective registry from which multiple research questions can be answered. In general, two main approaches will be used: (A) a data-driven (multi-)omics approach which aims to identify clusters of patients to predict clinical outcome, to improve (early) diagnosis, and/or to identify clusters of patients that share underlying pathophysiological processes; (B) a hypothesis-driven approach in which clinical parameters are tested for their (incremental) diagnostic and/or prognostic value.

Secondary outcome

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Study description

Background summary

Heart failure (HF) represents a heterogeneous range of clinical overlapping cardiomyopathy phenotypes, resulting from multifactorial environmental insults in the presence or absence of a genetic predisposition. A better understanding of (early) cardiomyopathy phenotypes, their underlying pathophysiological processes, and their related disease burden is key to pave the way for novel preventive and/or intervention studies.

Study objective

To optimize (early) diagnosis and risk-stratification of (early) cardiomyopathy phenotypes and to create a better understanding of underlying pathophysiological processes.

Study design

The Multicenter Cardiology Moniroting Platform (mCMP-registry) is an investigator-initiated multicenter (Maastricht University Medical Center,

University Medical Center Groningen, University Medical Center Utrecht, Zuyderland Medical Center) prospective observational registry including multi-omics (diagnostic) measurements performed as part of routine clinical care, bio-banking (optional), and yearly questionnaires (optional).

Study burden and risks

There is not any risk associated with the participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Referred to a cardiology or genetic department for heart failure like symptoms (as stated in the ESC 2016 Guidelines(3)) or for cardiac/cardiogenetic screening;
- Age >=16 years.

Exclusion criteria

- Unwillingness to participate or unable to give written informed consent (e.g. due to language barriers or severe intellectual disability).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2021
Enrollment:	40000
Type:	Actual

Ethics review

Approved WMO Date:	01-07-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-11-2021

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-11-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT04976348
CCMO	NL76585.068.21