

Onderzoek naar optreden van hartfalen na een hartaanval.

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The main aim of the current study is to identify novel pathophysiological pathways associated with the development of heart failure after an acute myocardial infarction.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26126

Bron

NTR

Verkorte titel

POST-MI

Aandoening

Hartfalen, myocardinfarct, genetica, biomarkers, bioinformatica, heart failure, myocardial infarction, genetics, bioinformatics, pathway

Ondersteuning

Primaire sponsor: Dr. Folkert W. Asselbergs, cardiologist

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Overige ondersteuning: ZonMw (Dutch organization for health research and innovation in health care)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Time till first hospitalization for heart failure or heart failure related mortality.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Heart failure (HF) is a major medical problem of the Western world, carrying a high morbidity, mortality and economic burden. An ischemic etiology such as an acute myocardial infarction (MI) underlies the development of HF in 70% of all cases. A substantial part of the susceptibility to develop ischemic HF is thought to be largely genetically based. However, genetic variants causing HF have only been identified in some families suffering from non-ischemic HF.

Objective:

The main aim of the current study is to identify novel pathophysiological pathways associated with the development of post-MI HF using genome-wide data and innovative bioinformatics approaches.

Study design:

The study is a multi-center, prospective, longitudinal, observational study.

Study population:

Patients admitted for treatment of a myocardial infarction are considered for inclusion.

Main study parameters/endpoints:

The primary outcome is the incidence of hospitalizations for heart failure. Secondary endpoints include reinfarction, stent thrombosis, arrhythmias, cardiac mortality, all-cause mortality and the combination of all these endpoints.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

This is an observational study. Participants will not be exposed to any risks associated with participation to the current study. Participants will not have any advantages or disadvantages by participating in the current study.

Doel van het onderzoek

The main aim of the current study is to identify novel pathophysiological pathways associated with the development of heart failure after an acute myocardial infarction.

Onderzoeksopzet

Total follow-up duration is 3-5 years.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients admitted with an acute myocardial infarction and candidates for primary PCI. A diagnosis of acute myocardial infarction is defined by chest pain suggestive for myocardial ischemia for at least 30 minutes with a time from onset of symptoms of less than 24 hours before hospital admission and an ECG with ST segment elevation of more than 0.1mV in 2 or more leads;
2. Minimum age 18 years;
3. Verbal followed by written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Presence of other serious medical conditions with a life expectancy of less than 6 months;
2. Unwilling to sign informed consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 01-02-2011
Aantal proefpersonen: 2400
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 08-02-2011
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34692
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2613
NTR-old	NTR2741
CCMO	NL29888.042.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34692

Resultaten

Samenvatting resultaten

N/A