

# A prospective cohort study to investigate the use of avb3-integrin imaging as a surrogate endpoint for therapeutic interventions in patients with myocardial infarction.

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N/A

<b>Ethische beoordeling</b>	Niet van toepassing
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON27835

### Bron

NTR

### Verkorte titel

N/A

### Aandoening

Myocardial infarction

Heart Failure

Hartinfarct

Hartfalen

### Ondersteuning

**Primaire sponsor:** Maastricht University Medical Center

**Overige ondersteuning:** Netherlands Heart Foundation

## Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

Ejection fraction.

## Toelichting onderzoek

### Achtergrond van het onderzoek

Heart failure (HF) is an increasing problem in the global population with a current prevalence in the US of approximately 5 million cases and 550,000 new cases being diagnosed each year. Myocardial infarction (MI) is the main cardiac insult leading to HF. Currently used drugs are already present for many years, and despite extensive animal research in the past decade, little progress is made in the development of new drugs for clinical use. The critical path initiative of the FDA stimulates and facilitates the development of new drugs, and the validation of biomarkers as surrogate endpoints is part of this initiative. This study aims to determine whether the extent of myocardial  $\alpha v\beta 3$  expression delineated by  $^{99m}\text{Tc}$ -NC100692 Injection scintigraphy imaging at 3 and 8 weeks after MI can be used as a surrogate endpoint for the outcome of therapeutic interventions, using existing and novel treatments (ACE-I vs. ACE-I+ARB vs. ACE-I+renin inhibition).

### Doel van het onderzoek

N/A

### Onderzoeksopzet

Imaging: 3 and 8 weeks after MI.

MRI: 3 weeks and 1 year after MI.

Echo: baseline.

### Onderzoeksproduct en/of interventie

Avb3 imaging at 3 and 8 weeks after MI.

3 groups which will receive;

1. Treatment with ACE inhibitor, or;
2. Treatment with ACE inhibitor + AT1R blocker, or;
3. Treatment with ACE inhibitor + Renin inhibitor.

## Contactpersonen

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. The subject has had no previous MI (a previous MI/scar could potentially result in tracer uptake and therefore interfere with the imaging outcome), presents with acute MI and has undergone coronary angiography during which percutaneous coronary intervention (PCI) or no intervention may be performed. The documentation of coronary anatomy and disease will be linked to the imaging outcome;

2. The subject is >18 years of age at study entry. Maximum age is 80 years, provided patients are in good condition;
3. The subject is able and willing to comply with study procedures and signed and dated informed consent is obtained, including permission to access coronary angiography records (see inclusion criterion No. 1), before any study procedure is carried out;
4. The subject is male, or a female who is either surgically sterile (has had a documented bilateral oophorectomy and/or documented hysterectomy), postmenopausal (cessation of menses for more than 1 year), non-lactating, or of childbearing potential for whom the result of a urine pregnancy test performed before administration of 99mTc-NC100692 Injection is negative to prevent harm to the potentially present unborn foetus;
5. The subject has been clinically stable (e.g., not experiencing continuing chest pain or haemodynamic instability) for at least 7 days before each imaging session with 99mTcNC100692 Injection\*. An unstable patient would be put to risk unnecessarily if subjected to an imaging study and will therefore be excluded;
6. The subject has an LVEF of >40% and <55% and is NYHA class 1-2. Patients with EF below 40% have to receive spironolactone/eplerenone according to the guidelines. This could interfere with the effect of the medication studied. In patients with EF above 55%, the infarct will be too small for significant tracer uptake.

\* This inclusion criterion will be checked at 3 and 8 weeks post-MI.

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

1. The subject was previously entered into this study or has participated in any other IMP study within 30 days of study entry, since this could interfere with the medications tested;
2. The subject is scheduled to receive another IMP from time of entry into this study until completion of the follow-up period after the second injection proposed for this study, since this could interfere with the medications and endpoints tested;
3. The subject has known allergies to any product used in this study or its constituents (e.g., para-amino benzoic acid);
4. The subject undergoes monitoring of occupational radiation exposure;
5. The subject presents with any other clinically active, serious, life-threatening disease with a life expectancy of less than 12 months, where participation in the study might compromise the management of the subject, or for any other reason that in the judgement of the

investigator(s) makes the subject unsuitable for participation of the study;

6. The subject is scheduled to have a revascularisation procedure (e.g., PCI or CABG) or cardiac transplant in the 30 days after study entry;

7. The subject participated in a research study using ionising radiation within 12 months of study entry, to prevent the patients for crossing the maximal yearly ionizing radiation exposure dosage;

8. Women sterilized by tubaligation.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Geneesmiddel

### Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2009
Aantal proefpersonen:	123
Type:	Verwachte startdatum

## Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

## Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register	ID
NTR-new	NL1673
NTR-old	NTR1774
Ander register	MEC azM/UM : 09-2-023
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Resultaten

### Samenvatting resultaten

N/A