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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27835

Source
NTR

Brief title
N/A

Health condition

Myocardial infarction
Heart Failure
Hartinfarct
Hartfalen

Sponsors and support

Primary sponsor: Maastricht University Medical Center
Source(s) of monetary or material Support: Netherlands Heart Foundation

Intervention

Outcome measures

Primary outcome

Ejection fraction.

Secondary outcome

N/A

Study description

Background summary

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 ávâ3/5 expression delineated by 99mTc-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).

Study objective

N/A

Study design

Imaging: 3 and 8 weeks after MI.

MRI: 3 weeks and 1 year after MI.

Echo: baseline.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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 smalle for significant tracer uptake.

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

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2009
Enrollment:	123
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL1673
NTR-old	NTR1774
Other	MEC azM/UM : 09-2-023
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A