Observational study;
An open-label, phase 2a imaging study to assess the utility off 99mTc-NC100692 injection in post-MI patients to predict risk of developing chronic heart failure.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22503

Source
Nationaal Trial Register

Brief title
N/A

Health condition

1. Myocardial Infarction (hartinfarct);

2. Heart Failure (hartfalen).

Sponsors and support

Primary sponsor: GE Healthcare Ltd., and its affiliates
Source(s) of monetary or material Support: GE Healthcare Ltd., and its affiliates

Intervention

Outcome measures

Primary outcome

To investigate the relationship between the myocardial (alpha)V(beta)3/5 expression by scintigraphy at 3 weeks, at 8 weeks and the change from 3 to 8 weeks after MI and signs of a poor post-MI prognosis based on occurrence of MACE and/or signs of developing HF evident from worsening in the measured echocardiography variables LVEF, WMA, LVID and MR in the 6-month and 12-month follow-up period.

Secondary outcome

To investigate the relationship between the myocardial (alpha)V(beta)3/5 expression by scintigraphy at 3 and 8 weeks after MI and the measured echocardiography variables LVEF, WMA, LVID and MR at 3 and 8 weeks.

To investigate the relationship between the myocardial (alpha)V(beta)3/5 expression by scintigraphy at 3 weeks, at 8 weeks and the change from 3 to 8 weeks after MI and other indices of post-MI prognosis such as Killip score (only assessed at pre-discharge), New York Heart Association (NYHA) class (assessed at predischarge, 3 weeks, 8 weeks, 6 months and 12 months) and blood levels of NT-proBNP (measured at predischarge, 6 months, 12 months).

Study description

Background summary

In order to determine a patient’s risk of developing full-blown HF, it is necessary to detect signs of the disease at an early, non-symptomatic stage and before substantial loss of myocardial function occurs, thereby enabling physicians to make effective therapeutic decisions (e.g., interventions and changes in medical treatment). The expression of (alpha)V(beta)3 on myofibroblasts is linked to active fibrosis, which is the hallmark of remodelling. This study will determine in 40 patients (with a run-in of 10 patients) whether detection of a particular pattern (e.g., persistent vs. non-persistent) of myocardial (alpha)V(beta)3/5 expression by 99mTc-NC100692 Injection scintigraphy imaging at 3 and 8 weeks after MI can be used to determine the longer-term risk of developing HF.

Study objective

The hypothesis of the present study is to demonstrate that detection of a particular pattern (e.g., persistent vs. non-persistent) of myocardial (alpha)V(beta)3/5 expression by

scintigraphy imaging at 3 and 8 weeks after MI can be used to determine the longer-term risk of developing heart failure (HF).

Study design

N/A

Intervention

Baseline:

Nuclear myocardial perfusion imaging, at rest and stress, using a thallium 201- or technetium 99m-labelled agent and according to the hospital's routines, to establish the extent of myocardium remaining non-perfused.

All subjects will receive administration of
99mTc-NC100692 Injection at 3 and 8 weeks after MI and undergo SPECT imaging. Injection of 5.5 ml of 99mTc-NC100692 Injection at a rate of 2-4 ml per second. Each subject will receive +/-69 µg of NC100692 and a maximum 99mTc activity of 1 GBq/injection. An intravenous line (large bore catheter) should be established with a cannula valve for administration of 99mTc-NC100692 Injection. A suitable injection site will be chosen for each subject. After administration, the line should be flushed with 5 ml of Sodium Chloride (0.9% w/v). Subjects will receive the first injection 3 weeks after MI and the second injection 8 weeks after MI (nominal time points that may vary by ±3 days).

Echocardiography ± Doppler will be performed at all time points (baseline, 3+8weeks, 6+12months) to establish post-MI "baseline" values for left ventricular
ejection fraction (LVEF), wall motion abnormalities (WMA), left ventricular internal dimensions (LVID) and mitral valve regurgitation (MR).

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Eligibility criteria

Inclusion criteria

Subjects may be included in the study if they meet all of the following criteria:

1. The subject has had no previous MI, presents with acute MI and has undergone coronary angiography during which percutaneous coronary intervention (PCI) or no intervention may be performed.

2. The subject is >18 years of age at study entry.

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 IMP is negative;

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 99mTc-NC100692 Injection*
* this inclusion criterion will be asked at 3 and 8 weeks post-MI.

Inclusion criterion for subjects with a presumed high post-MI likelihood of developing heart failure:

6. The subject has an LVEF of <40% and/or is NYHA class 3-4;

Inclusion criterion for subjects with a presumed low post-MI likelihood of developing heart failure:

7. The subject has an LVEF of >40% and is NYHA class 1-2.

Exclusion criteria

Subjects must be excluded from participating in this study if they meet any of the following criteria:

1. The subject was previously entered into this study or has participated in any other investigational medicinal product (IMP) study within 30 days of study entry.

2. The subject is scheduled to receive another IMP from time of entry into this study until completion of the follow-up period proposed for this study.

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 or 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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2005
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	20-09-2007
Application type:	First submission

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	NL1039
NTR-old	NTR1072
Other	: protocol number ANG207; EudraCT 2005-002153-42
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A