A phase III study to compare SonoVue® enhanced myocardial echocardiography (MCE) to single photon emission computerized tomography (ECG-GATED SPECT), at rest and at peak of low-dose Dipyridamole stress test, in the assessment of significant coronary artery disease (CAD) in patients with suspect or known CAD using Coronary Angiography as Gold Standard

Published: 17-03-2008
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see separate synopsis

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON31731

Source
ToetsingOnline

Brief title
BR1-125

Condition

- Coronary artery disorders

Synonym
coronairy artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Bracco Imaging S.p.a.
Source(s) of monetary or material Support: Bracco Imaging S.p.a.;Milaan Italie

Intervention

Keyword: coronary artery disease, myocardial echocardiography

Outcome measures

Primary outcome

see separate synopsis

Secondary outcome

see separate synopsis

Study description

Background summary

see separate synopsis

Study objective

see separate synopsis

Study design

see separate synopsis

Intervention

see separate synopsis

Study burden and risks

see separate synopsis

Contacts

Public
Bracco Imaging S.p.a.

Via Folli 50
I-20134 Milaan
Italie
Scientific
Bracco Imaging S.p.a.

Via Folli 50
I-20134 Milaan
Italie

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Having at least 18 years of age.
* Having a known or suspected coronary artery disease (CAD) indicated for stress ECGgated SPECT and/or coronary angiography to clarify whether they have a clinical significant coronary stenosis (*70%).

* Having provided written Informed Consent and willing to comply with protocol requirements.

Exclusion criteria

Has any clinically unstable cardiac condition prior to SonoVue® administration such as:
- evolving or ongoing myocardial infarction,
- a history of acute myocardial infarction or PCI within the previous 3 months,
- worsening of typical angina at rest within the previous 7 days,
- significant worsening of cardiac symptoms within the previous 7 days,
- recent coronary artery intervention or other factors suggesting clinical instability (e.g., recent deterioration of ECG, laboratory or clinical findings),
- acute cardiac failure, class III/IV cardiac failure,
- severe cardiac rhythm disorders (ventricular tachycardia sustained and not sustained in combination with symptoms).
* Has any contra-indications to dipyridamole or aminophylline (e.g. hypersensitivity to xanthines) according to each agent*s package insert.
* Has any known allergy to one or more of the ingredients of the investigational product.
* Has a previous Coronary Artery By-pass.
* Has any revascularization procedure or change of clinical status that may warrant a change in their status of CAD among the clinical testing under evaluation (coronary angiography, MCE or ECG-GATED SPECT).
* Has used methylated xanthines (chocolate, caffeine * including coffee, tea, and cola drinks), phosphodiesterase inhibitor drugs such as aminophylline or dipyridamole within 24 hours prior SonoVue® enhanced echocardiography or SPECT.
* Has not visualization of left ventricle at basal echocardiography.
* Has received an investigational compound within 30 days before admission into this study.
* Has any medical condition or other circumstances which would significantly decrease the chances of obtaining reliable data, achieving study objectives, or completing the study and/or post dose follow-up examinations.
* Is determined by the Investigator that the subject is clinically unsuitable for the study.
* Is a pregnant or lactating female. Exclude the possibility of pregnancy:
* by testing on site at the institution (serum or urine *HCG) within 24 hours prior to the start of investigational product administration,
- by surgical history (e.g., tubal ligation or hysterectomy),
- post menopausal with a minimum 1 year without menses.

Study design

Design

Study phase: 3

Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2008
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	17-03-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	10-07-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	16-07-2009
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2007-003492-39-NL
CCMO	NL20857.029.08