Duplex ultrasound method to assess patency in the proximal part of the LIMA of Y-bypass grafts in late follow up related to multislice ct-scan after CABG.

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To assess whether the non-invasive duplex method can reliably determine diameters and flow characteristics in the LIMA origin of LIMA-LAD versus Y-bypass grafts late after CABG in relation to-the number of distal anastomosis-the adaptation to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30675

Source
ToetsingOnline

Brief title
Duplex

Condition

- Coronary artery disorders
- Vascular therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
patency: functionality

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Additionele kosten verrekening via Thoraxcentrum Research BV

Intervention

Keyword: ct-scan, Duplex, LIMA, Y graft

Outcome measures

Primary outcome

Diastolic peak velocity of the LIMA graft

Systolic peak velocity of the LIMA graft

Diastolic velocity integral of the diastolic phase in the cardiac cycle.

Systolic velocity integral of the systolic phase in the cardiac cycle.

Diastolic/systolic peak velocity ratio

Diastolic/total (systolic + diastolic) velocity integral ratio

Secondary outcome

Not applicable

Study description

Background summary

The use of the left internal mammary artery (LIMA) as a bypass graft to revascularize the left anterior descending artery (LAD) has improved the durability of coronary artery bypass grafting.
To evaluate the long-term performance of the LIMA graft an accurate non-invasive functional test without contrast of the LIMA graft is important. Several methods have been described since the 1980*s to assess LIMA graft patency. At present invasive angiography is the gold standard. However, invasive angiography also has disadvantages i.e. the inability to quantify severe vulnerable plaques, inadequate contrast filling especially into the distal coronary artery parts and small side branches, catheter-induced spasm of

the LIMA, underestimation of eccentric plaques and overprojection of coronary arteries. There are no validated non-invasive methods without contrast available to control LIMA graft patency directly.

Study objective

To assess whether the non-invasive duplex method can reliably determine diameters and flow characteristics in the LIMA origin of LIMA-LAD versus Y-bypass grafts late after CABG in relation to

-the number of distal anastomosis

-the adaptation to hyperaemic response

Study design

It is an observational, diagnostic and comparing investigation between non-invasive duplex echocardiography and ct-scans.

Study burden and risks

1-Electrographic control -- 15 minutes
2-Read and sign the *informed consent* letter -- 10 minutes
3-Duplex at rest -- 20 minutes
4-Duplex in modified hyperemic response -- 10 minutes
5-Complete a short questionnaire --10 minutes
6-64-slice CT-scan control -- 30 minutes

Risk profile; very low

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam

Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients who underwent CABG 10 years ago will be included in the study to undergo both a duplex and CT-scan.

Exclusion criteria

Redo surgery, serious co-morbidity (malignancy, previous chest irradiation), infarction of the bypassed region, combined cardiac surgery, subclavian artery stenosis, renal failure (creatinine >= 120 µmol/l), irregular cardiac rhythm, allergic to iodine and pregnancy.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2007
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	12-03-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL13011.078.06