Coupler Study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20311

Source
Nationaal Trial Register

Brief title
Coupler Study

Health condition

cabg, total arterial revascularization

Sponsors and support

Primary sponsor: Catharina Hospital Eindhoven.

Sponsor: none
Source(s) of monetary or material Support: Catharina Hospital Eindhvoen

Intervention

Outcome measures

Primary outcome

1. Acute Patency: The presence of acute patency of the distal anastomoses as determined by flow measurements intraoperatively;

2. Chronic Patency: The presence of patency of the end-to-end radial-lita anastomoses as determined by multislice CT - Scan at 3 months;

3. Incidence of device related Adverse Events.

Secondary outcome

N/A

Study description

Background summary

Rationale:

Coronary Artery ByPass Grafting (CABG) procedures are typically employed to achieve revascularization of the heart. Different conduits can be used for bypass grafting.

In the last two decades, the radial artery (RA) has emerged as a major alternative arterial conduit in preference to saphenous vein grafts or when traditional grafts are unsuitable or unavailable in coronary artery bypass grafting (CABG). However, to optimize the use of RA as a coronary bypass conduit, several technical considerations have been emphasized.

One technique, as performed in our hospital, is the use of extended radial artery conduit for revascularization, with the use of both the left internal thoracic artery (LITA) and the RA, with a hand sewn end-to-end anastomoses. Though disadvantages of conventional suturing techniques for end-to-end anastomoses are; intraluminal suture material in the anastomoses, time consuming, difficulties in vessel size mismatch corrections and surgeon dependent quality of the anastomotic configuration. A well known and well described anastomotic device, which is used extensively in plastic surgery (and standard practice for some plastic surgical procedures in our hospital) and neurosurgery to facilitate anastomoses; is the GEM Microvascular Anastomotic COUPLER System. The system is specifically designed for use in the anastomosis of veins and arteries in microsurgical procedures. The GEM COUPLER is intended for use with veins and arteries having an outside diameter no smaller than 0.8mm and no larger than 4.3mm and a wall thickness of 0.5mm or less.

Objective:

The purpose of this study is to demonstrate patency of the GEM COUPLER system to facilitate the LITA-RA end-to-end anastomosis in CABG procedures.

Study design:

Patients planned to undergo a CABG procedure and agree to participate in the study (signed informed consent) will be included for the study. The surgery will be a routine CABG procedure, performed with the routine Extended Radial Artery Conduit Technique and extension of the radial artery with GEM COUPLER System, and according to the standard hospital practice;

Post procedure , the patients will be treated according to the hospital standard practice. The patients will be asked to return to a follow up visits at 3 months post hospital discharge, at which time an ECG will be performed, and data on blood pressure, anginal status and anticoagulant medications will be collected. At the 3-month follow-up visit, also a Multislice Computed Tomography (MS – CT scan) will be performed and patency information will be recorded on the study vessel.

Study objective

Use of the GEM microvascular anastomotic coupler is feasible in coronary artery bypass procedures with the extended radial artery technique and the coupler anastomoses is patent after 3 months.

Study design

N/A

Intervention

Standard CABG procedure, with extended radial artery technique, with the radial-lita anastomoses facilitated with the GEM flow microvascular coupler.

Contacts

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Eligibility criteria

Inclusion criteria

1. Able to give informed consent able to understand the intent and clinical meaning of the study as well as its implication;

2. Patients between 18 years and 70 years old;

3. Willing and able to have follow-up visits and examinations;

4. Standard Euroscore < 2.

Exclusion criteria

1. Procedure is done as an emergency operation;

2. Unable to meet study requirements, i.e. mobility challenge;

3. Participation in any other clinical trial;

4. Pregnancy;

5. Concomitant with heart valve surgery;

6. History of any cardiac surgery other than PTCA and stent placement;

7. History of IABP within the last 30 days;

8. History of atrial fibrillation;

9. Congestive heart failure or been classified NYHA Class IV in the last 30 days;

10. History of bleeding disorder or history of thromboembolic disease requiring anticoagulation therapy;

11. Hemodynamically unstable;

12. History of acute or chronic dialysis;

13. Creatinine level of > 200 mmol/ml or 2,3 mg/dL in the last 30 days;

14. Documented or suspected acute systemic infection;

15. Need for immunosuppressive therapy;

16. Cerebrovascular accident within the last 2 weeks;

17. Allergy or other contraindication for aspirin or other anticoagulant/antiplatelet therapy;

18. Allergy or other contraindication for Iomeron® contrast agent;

19. Allergy or other contraindication for metoprolol.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-03-2013
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	NL3743
NTR-old	NTR3914
Other	NJV : 190108
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A