Cardica C – Port xA ™ Anastomotic System

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21446

Source
Nationaal Trial Register

Brief title
Cardica C - Port xA

Health condition

angina pectoris, coronary disease, CABG, Sutureless anastomoses, vascular connector

Sponsors and support

Primary sponsor: Dr. Berreklouw
Drs. J. ter Woorst
Drs. N.J. Verberkmoes
Source(s) of monetary or material Support: Mr. Hans Marinus
LST Europe
Weiseind 10
5673 BS Nuenen

Intervention

Outcome measures

Primary outcome

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

b. Chronic: The presence of patency of the distal anastomoses as determined by multislice CT - Scan at 12 months.

c. Incidence of device related Adverse Events

Secondary outcome

a. Time required for system loading and for the distal anastomosis to be completed.

b. User friendliness of the system

c. Abbreviated ischemic time using Cardica ™ C - Port xA

Study description

Background summary

Coronary Artery Disease (CAD) is the leading cause of death in our society. Either Percutaneous Transluminal Coronary Angioplasty (PTCA), with or without stenting, or Coronary Artery ByPass Grafting (CABG) procedures are typically employed to achieve revascularization of the heart. The Cardica ™ C - Port xA is intended for use in CABG procedures for creating a rapid sutureless end to side directional distal anastomosis between a grafted vessel (vein or artery) and the coronary artery. The Cardica ™ C - Port xA has three possible advantages compared to the standard suturing technique: The Cardica ™ C - Port xA may provide a method for standardizing the anastomosis procedure. Usage of the Cardica ™ C - Port xA may shorten the actual “suturing” period of 10-25 minutes and the period of myocardial ischemia associated with local occlusion of a coronary vessel in OPCAB procedures. For OPCAB cases, shortening the time needed for graft connection will reduce the period of hemodynamic instability frequently associated with heart displacement needed for back wall vessels exposure. Finally, the anastomosis created with a C-Port xA is compliant as opposed to an anastomosis created using the standard running suturing technique, where the anastomosis is non-compliant and is restricted in its ability to expand with increasing blood flow requirements.

Study objective

To demonstrate equivalency of the Cardica ™ C - Port xA anastomosis compared to hand sutured anastomoses in patients undergoing CABG with respect to 12 months patency at distal anastomosis site.

Study design

1. Perioperative / In Hospital

2. 6 month follow-up (clinical)

3. 12 month follow-up (clinical and CT-scan)

Intervention

Coronary Bypass Surgery

Contacts

Public
Catharina Hospital
Dep. Cardiothoracic Surgery, research and development

Berreklouw
Michelangelolaan 2

Eindhoven 5623 EJ
The Netherlands
+31 (0)40 2398680
Scientific
Catharina Hospital
Dep. Cardiothoracic Surgery, research and development

Berreklouw
Michelangelolaan 2

Eindhoven 5623 EJ
The Netherlands
+31 (0)40 2398680

Eligibility criteria

Inclusion criteria

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

2. Patients 18 years old or older.

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. Not a standard CABG operation or is 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. Congestive heart failure or been classified NYHA Class IV in the last 30 days.

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

10. Hemodynamically unstable.

11. History of acute or chronic dialysis.

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

13. Documented or suspected acute systemic infection.

14. Need for immunosuppressive therapy.

15. Cerebrovascular accident within the last 2 weeks.

16. Allergy or other contraindication for aspirin or other anticoagulant/antiplatelet therapy

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2008
Enrollment:	78
Type:	Actual

Ethics review

Positive opinion

Date:	17-08-2008
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	NL1349

Register	ID
NTR-old	NTR1409
Other	: NJV_130679
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A