Cardica C – Port xA ™ Anastomotic System

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21446

Bron
Nationaal Trial Register

Verkorte titel
Cardica C - Port xA

Aandoening

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

Ondersteuning

Primaire sponsor: Dr. Berreklouw
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Overige ondersteuning: Mr. Hans Marinus
LST Europe
Weiseind 10
5673 BS Nuenen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. Perioperative / In Hospital

2. 6 month follow-up (clinical)

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

Onderzoeksproduct en/of interventie

Coronary Bypass Surgery

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2008
Aantal proefpersonen:	78
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	17-08-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1349
NTR-old	NTR1409
Ander register	: NJV_130679
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A