Cardica C - Port xA * Anastomotic System

Published: 15-05-2008
Last updated: 20-06-2024

The purpose of this study is 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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON31599

Source
ToetsingOnline

Brief title
C - Port Connector

Condition

- Cardiac therapeutic procedures

Synonym
coronary artery bypass operation

Research involving
Human

Sponsors and support

Primary sponsor: LST Europe bv.
Source(s) of monetary or material Support: LST Europe bv

Intervention

Keyword: Anastomoses, Coronary, Distal, Sutureless

Outcome measures

Primary outcome

Efficacy

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

The purpose of this study is 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

Patients planned to undergo a CABG procedure and agree to participate in the study (signed informed consent) will be randomized to either the investigational device or to a conventional hand suture technique group. The operation will be a routine CABG procedure according to the hospital practice; the only difference is the creation of the anastomosis using the device in patients randomized to the investigational device group. Post operation, the patients will be treated according to the Hospital normal practice. The patients will be asked to return to a follow up visits at 6 months post hospital discharge, at which time an ECG will be performed, blood pressure, anginal status and anticoagulant medications will be collected. At 12 - month follow up visit a Multislice Computed Tomography (MS - CT scan) will be performed and patency information recorded on all study vessels. Clinical evaluation, ECG, blood pressure, anginal status and cardiovascular and anti-coagulant medication will be recorded.

Intervention

Facilitating distal anastomoses with mechanical connector device.

Study burden and risks

Involved with the procedures are similar to risks in standard CABG procedures, in particular: death, during and post procedure myocardial infarction, cerebrovascular event, post operative bleeding and tamponade, coronary occlusion (thrombosis) or spasm, arterial dissection, sternal or other wound infection, sepsis, need for CABG reoperation, arrhythmia, drug induced side effects, aortic aneurysm, pneumonia, stress ulcer or GI bleeding and post CABG anginal syndrome. Total procedure time for deployment is expected to be 30 seconds. The loading of the device is normally done prior to cardiopulmonary bypass. The loading time may vary with surgical training, and realistically be within 1 and 10 minutes. However, the patient will not be exposed to prolonged bypass time because of this.

There are general risks associated with a CT scan. Patients will be exposed to radiation during the CT - scan which could amount as maximum up to 5,5 +/- 3.1 mSv. For comparison, the average annual radiation exposure that a person can expect to experience from natural environmental causes in the Netherlands is approximately 2,1 mSv per year. And yearly dose limitation for people working in radiation rich environments, such as radiologists, is determined by law at 20 mSv

Contacts

Public
LST Europe bv.

Weiseind 10
5673 BS Nuenen
Nederland
Scientific
LST Europe bv.

Weiseind 10
5673 BS Nuenen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Undergoing CABG
- Able to give informed consent able to understand the intent and clinical meaning of the study as well as its implication.

- Patients 18 years old or older
- Willing and able to have follow-up visits and examinations
- Standard Euroscore < 2

Exclusion criteria

- Procedure is done as an emergency operation
- Unable to meet study requirements, i.e. mobility challenge
- Participation in any other clinical trial
- Pregnancy
- Not a standard CABG operation or is concomitant with heart valve surgery
- History of any cardiac surgery other than PTCA and stent placement
- History of IABP within the last 30 days
- Congestive heart failure or been classified NYHA Class IV in the last 30 days
- History of bleeding disorder or history of thromboembolic disease requiring anticoagulation therapy
- Hemodynamically unstable
- History of acute or chronic dialysis
- Creatinine level of > 200 mmol/ml or 2,3 mg/dL in the last 30 days
- Documented or suspected acute systemic infection
- Need for immunosuppressive therapy
- Cerebrovascular accident within the last 2 weeks
- Allergy or other contraindication for aspirin or other anticoagulant/antiplatelet therapy

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-06-2008
Enrollment:	78
Type:	Actual

Medical products/devices used

Generic name:	Cardica C - Port xA □ Anastomotic System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-05-2008
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL21331.060.08