Corlink long term follow up

Published: 12-10-2010
Last updated: 03-05-2024

The purpose of this audit is to demonstrate the long-term patency of Corlink device compared to the standard "coronary artery bypass grafting (CABG). We also offer this to patients in the study population an extra quality

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON34024

Source
ToetsingOnline

Brief title
Corlink long term

Condition

- Cardiac therapeutic procedures

Synonym
coronary artery bypass grafting patency

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: CABG, Corlink, Multislice CT-scan

Outcome measures

Primary outcome

Patency of the bypass grafts

Secondary outcome

n.a.

Study description

Background summary

From 2001 to 2004 the research department of cardiothoracic surgery participated in the Multi-center trial Corlink. The study took place in our center and in the Amphia Hospital Breda. In summary this was an experimental trial to the applicability of adhesion-free connections in the coronary artery surgery. One of the most important primary endpoints of this study was the so-called short-term patency of coronary bypass grafts (patency = good blood flow in the diversion). The study found that using a coronary angiogram. For more details, I refer you to the Protocol to METC METC No # M00/1616 & M03/1359 #. At the time the study was successfully completed.

However, as already mentioned above, patients participated in an experimental trial. Because we always strive for quality care, we believe that the participants in this study are entitled to a long-term control.
Until recently it was not really possible without an invasive coronary angiogram to do an audit of coronary bypass surgery. However, we recently have this opportunity. This is today possible using the 256 multi-slice computed tomography. For that reason we would then have patients who participated in the study Corlink now want a quality offer.

Study objective

The purpose of this audit is to demonstrate the long-term patency of Corlink device compared to the standard "coronary artery bypass grafting (CABG). We also offer this to patients in the study population an extra quality

Study design

We will we distill from our database, which patients in the study population are still alive. These patients we through a letter or telephone call for

additional review. The audit will include an outpatient clinic where we visit a short history and complete physical examination performed. In addition, patients with written informed consent a CT scan of the heart undergo.

Study burden and risks

Minimal impact and risk.

Default risk due to contrast administration in CT scan.
Standard radiation exposure due to CT

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2
5623 EJ Eindhoven
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
5623 EJ Eindhoven
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Participation in the Corlink Study

Exclusion criteria

Atrialfibrilation
Severe renale dysfunction
coronary angiogram in past year
cardiac ct-scan in past year
re-cabg

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2011
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	12-10-2010
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	NL32826.060.10

Study results

Date completed: 31-12-2011

Actual enrolment: 20

Summary results
Trial is onging in other countries