Antispasmodic agents for radial artery conduit in CABG

Published: 25-09-2013
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Objective: The main objective of the study is to compare the antispasmodic effect of two calcium channel blocker (verapamil and nicardipine) on the prepared radial artery conduit.

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

Summary

ID

NL-OMON38886

Source
ToetsingOnline

Brief title
Antispasm Radial

Condition

- Vascular therapeutic procedures

Synonym
Spasm

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: maatschap cardiochirurgie

Intervention

Keyword: CABG, Radial, Spasm

Outcome measures

Primary outcome

Main study parameters/endpoints: The main endpoint of the study is the mean amount of free flow through the radial artery conduit. This is measured directly after harvesting the radial artery by allowing a free flow of both solution through the conduit into an empty bowl. The mean amount of the solution (in ml) collected in one minute is calculated. This is considered as the mean free flow (ml/min) through the conduit.

Secondary outcome

none

Study description

Background summary

Rationale: The use of topical application of vasodilators such as calcium channel blockers and/or nitroglycerines leads to possible improvement of the blood flow via the radial artery conduit by avoiding perioperative spasm.

Study objective

Objective: The main objective of the study is to compare the antispasmodic effect of two calcium channel blocker (verapamil and nicardipine) on the prepared radial artery conduit.

Study design

Study design: A prospective randomized non-blind mono-centre study

Intervention : After harvesting the radial artery and before performing the anastomoses, topical application of two different vasodilator solutions will be performed. One solution is being used in the standard practice of our department and contains 10 mg verapamil. In the other solution, verapamil is

replaced by nicardipine (10 mg).

Study burden and risks

not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients undergoing isolated or combined CABG whereby the radial artery is used as a conduit with or without the use of other conduits.

Exclusion criteria

Emergency operations

Study design

Design

Study type:	Observational non invasive
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):	14-10-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	25-09-2013
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	NL44701.060.13