

# Antispasmodic agents for radial artery conduit.

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON23784

### Source

Nationaal Trial Register

### Brief title

Antispasm Radial

### Health condition

Treatment radial conduits in coronary artery bypass grafting

## Sponsors and support

**Primary sponsor:** none

**Source(s) of monetary or material Support:** No funding

## Intervention

## Outcome measures

### Primary outcome

Comparison between verapamil and nicardipine in preventing spasm and increasing direct free flow through the radial artery conduit.

### Secondary outcome

Effect of the two drugs on the incidence of perioperative ischemia and infarction.

## Study description

### Background summary

Rationale:

The use of local 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 in comparison with the local application of saline solution.

Objective:

The main objective of the study is to investigate if the local application of vasodilators would improve the immediate flow through the prepared radial artery conduit.

Study design:

A prospective randomized non-blind mono-centre study.

Study population:

Patients who are scheduled for undergoing coronary artery bypass surgery with the use of the radial artery with or without other conduits.

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).

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.

Nature and extent of the burden and risks associated with participation: No risk is expected for patients who participate in this study. A possible benefit for the patients is the better antispastic action of nicardipine and therefore less incidence of perioperative ischemia.

## **Study objective**

Our hypothesis is that using nicardipine instead of verapamil in the vasodilation solution would increase the free flow.

## **Study design**

N/A

## **Intervention**

This is a prospective randomized non-blinded study containing two groups of patients. In one group, the radial artery will be treated topically with the solution used in our daily practice which contains verapamil. In the other group, the same solution is used after replacing verapamil with nicardipine. Topical application of either solutions takes place only after harvesting the radial artery and before performing the anastomoses. After measuring the flow manually, the surgeon may use the radial artery conduit in his own manner for performing the anastomoses.

## **Contacts**

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## Eligibility criteria

### 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 Operation.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2013
Enrollment:	40
Type:	Anticipated

## Ethics review

Not applicable	
Application type:	Not applicable

## 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	NL3793
NTR-old	NTR3966
Other	: HIO2013
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A