The effect of electrical neurostimulation on collateral perfusion during acute coronary occlusion.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22491

Source
Nationaal Trial Register

Brief title
N/A

Health condition

1. Angina;

2. angioplasty;

3. electrical neurostimulation;

4. coronary collaterals.

Sponsors and support

Primary sponsor: N/A

Intervention

Outcome measures

Primary outcome

The primary endpoint was collateral perfusion, the Pw/Pa ratio. This was measured during a 1-minute balloon inflation during PCI. The Pw/Pa ratio was measured in each patient during two ischemic episodes. To compare the Pw/Pa ratio with and without electrical neurostimulation. The Pw/Pa ratio is measured intracoronary, using a pressure wire.

Secondary outcome

N/A

Study description

Background summary

Electrical neurostimulation can be used to treat patients with refractory angina, it reduces angina and ischemia. Previous data have suggested that electrical neurostimulation may alleviate myocardial ischaemia through increased collateral perfusion. We investigated the effect of electrical neurostimulation on functional collateral perfusion, assessed by distal coronary pressure measurement during acute coronary occlusion. We sought to study the effect of electrical neurostimulation on collateral perfusion in a cross-over design.

Methods:

Sixty patients with stable angina and significant coronary artery disease planned for elective percutaneous coronary intervention were split in two groups. In all patients two balloon inflations of 60 seconds were performed, the first for balloon pre-dilatation of the lesion (first episode), the second for stent delivery (second episode). The Pw/Pa ratio (wedge pressure / aortic pressure) was measured during both ischaemic episodes. Group 1 received active neurostimulation during the first episode, group 2 received active neurostimulation during the second episode.

Study objective

Neurostimulation can improve collateral perfusion measured as a Pw/Pa ratio, during acute coronary occlusione.

Study design

N/A

Intervention

The intervention was electrical neurostimulation, during 5 minutes before and during the 1-minute ischemic episode. Within a patient we measured during the 1-minute ischemic episode the collateral perfusion, with and without electrical neurostimulation. The ischemic episode was established by balloon inflation during elective PCI.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with stable angina;

2. Evidence of myocardial ischemia;

3. Planned for elective percutaneous coronary intervention.

Exclusion criteria

1. Recent myocardial infarction;

2. Prior coronary artery bypass grafting;

3. Undtable angina;

4. Conduction disturbances;

5. Pacemaker;

6. Internal cardio defibrillator.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2006
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	18-04-2007
Application type:	First submission

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	NL933
NTR-old	NTR958
Other	:
ISRCTN	ISRCTN81465865

Study results

Summary results
BMC Cardiovasc Disord. 2007 Jun 27;7:18.