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

Submission date	Recruitment status No longer recruiting Overall study status	Prospectively registered		
30/05/2007		☐ Protocol		
Registration date		Statistical analysis plan		
30/05/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
04/07/2007	Circulatory System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Study objectives

Neurostimulation can improve collateral perfusion measured as a coronary wedge pressure (Pw) /aortic pressure (Pa) ratio, during acute coronary occlusion.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised, active controlled, crossover trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Angina pectoris, electrical neurostimulation, coronary collaterals, angioplasty

Interventions

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

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s))

No secondary outcome measures

Completion date

10/05/2006

Eligibility

Key inclusion criteria

- 1. Patients with stable angina
- 2. Evidence of myocardial ischaemia
- 3. Planned for elective Percutaneous Coronary Intervention (PCI)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

- 1. Recent myocardial infarction
- 2. Prior coronary artery bypass grafting
- 3. Undtable angina
- 4. Conduction disturbances
- 5. Pacemaker
- 6. Internal cardio-defibrillator

Date of first enrolment

10/01/2006

Date of final enrolment

10/05/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Thorax Centre

Groningen Netherlands 9713 GZ

Sponsor information

Organisation

University Medical Centre Groningen (UMCG) (The Netherlands)

ROR

https://ror.org/03cv38k47

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Centre Groningen (UMCG) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	27/06/2007		Yes	No