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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures
No secondary outcome measures

Overall study start date
10/01/2006

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

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)

Sponsor details
Thorax Centre
Department of Cardiology
Groningen
Netherlands
9700 RB

Sponsor type
Hospital/treatment centre

Website
http://www.umcg.nl/azg/nl/english/azg/

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Centre Groningen (UMCG) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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