

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

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

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestopt       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON22491

### Bron

NTR

### Verkorte titel

N/A

### Aandoening

1. Angina;
2. angioplasty;
3. electrical neurostimulation;
4. coronary collaterals.

### Ondersteuning

**Primaire sponsor:** N/A

### Onderzoeksproduct en/of interventie

## **Uitkomstmaten**

### **Primaire uitkomstmaten**

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.

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

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.

### **Doel van het onderzoek**

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

### **Onderzoeksopzet**

N/A

### **Onderzoeksproduct en/of interventie**

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.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with stable angina;
2. Evidence of myocardial ischemia;
3. Planned for elective percutaneous coronary intervention.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

## Onderzoeksopzet

### Opzet

|                  |                         |
|------------------|-------------------------|
| Type:            | Interventie onderzoek   |
| Onderzoeksmodel: | Cross-over              |
| Toewijzing:      | Gerandomiseerd          |
| Blinding:        | Open / niet geblindeerd |
| Controle:        | Geneesmiddel            |

### Deelname

|                         |                       |
|-------------------------|-----------------------|
| Nederland               |                       |
| Status:                 | Werving gestopt       |
| (Verwachte) startdatum: | 10-01-2006            |
| Aantal proefpersonen:   | 60                    |
| Type:                   | Werkelijke startdatum |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 18-04-2007       |
| Soort:          | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register       | ID             |
|----------------|----------------|
| NTR-new        | NL933          |
| NTR-old        | NTR958         |
| Ander register | :              |
| ISRCTN         | ISRCTN81465865 |

## Resultaten

### Samenvatting resultaten

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