Adenosine Administration during and after Primary percutaneous coronary intervention in acute myocardial infarction – a Randomized Controlled Trial (ADAPT).

Gepubliceerd: 27-09-2007 Laatst bijgewerkt: 18-08-2022

Intracoronary adenosine injections will lead to a significant reduction in the amount of residual ST-segment deviation.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22898

Bron
Nationaal Trial Register

Verkorte titel
ADAPT

Aandoening

1. Percutaneous coronary intervention;

2. Myocardial infarction;

3. Reperfusion therapy.

Ondersteuning

Primaire sponsor: University Medical Center Groningen,
Thoraxcenter, Dept Cardiology.
Overige ondersteuning: University Medical Center Groningen,
Thoraxcenter, Dept

Cardiology.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Residual ST-segment deviation at 30 to 60 minutes after the procedure.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Primary percutaneous coronary intervention (PCI) has been associated with a high incidence of diminished myocardial perfusion, despite a patent epicardial vessel. This so-called no-reflow phenomenon, can result in larger infarct size, less recovery of left ventricular ejection fraction, and increased mortality.
Objectives: The primary objective is to investigate the effect of intracoronary (IC) injection of adenosine on myocardial perfusion. We hypothesize that IC injection of adenosine during and after PCI will reduce residual ST-segment deviation at 30 to 60 minutes after the procedure by 25%. Secondary objectives include the investigation of the impact of adenosine in improving procedural outcome, as assessed by coronary angiography, electrocardiography and clinical outcome.

Study design: The study is a single-center, prospective, randomized trial with blinded evaluation of endpoints.

Study population: All patients with acute myocardial infarction and candidates for primary PCI admitted to the University Medical Center of Groningen are considered for participation in the study. The planned inclusion of the study involves 450 patients.

Intervention: The primary treatment is thrombus aspiration followed by stent implantation. During and after PCI, patients are assigned to treatment with IC injections of adenosine or placebo.
Main study outcome parameters: The primary outcome parameter is residual ST-segment deviation at 30 to 60 minutes after the procedure. Secondary outcome parameters are: post-procedural TIMI flow, myocardial blush grade and distal embolization on coronary angiography, ST-segment deviation resolution, enzymatic infarct size and clinical outcome at 30 days and 12 months.

Risks associated with participation: Currently available clinical evidence documents a risk profile of additional IC injections of adenosine comparable to a standard PCI procedure.

Implications: If IC adenosine injections lead to a significant reduction in the amount of residual ST-segment deviation, it will give support to the use of IC adenosine as part of the standard approach in patients with AMI.

Doel van het onderzoek

Intracoronary adenosine injections will lead to a significant reduction in the amount of residual ST-segment deviation.

Onderzoeksproduct en/of interventie

Intracoronary adenosine injection versus placebo.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. A diagnosis of acute MI defined by chest pain suggestive for myocardial ischemia for at least 30 minutes, with a time from onset of symptoms of less than 12 hours, before hospital admission.

2. An ECG with ST- segment deviation of more than 0.1 mV in 2 or more leads.

3. Thrombus aspiration performed.

4. Verbal followed by written informed consent.

5. 18 years or older.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Need for emergency coronary artery bypass grafting (CABG).

2. Presence of cardiogenic shock.

3. Known existence of a life-threatening disease with a life expectancy of less than 6 months.

4. Receiving pharmacotherapy for chronic obstructive pulmonary disease (COPD).

5. Inability to provide informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	22-08-2007
Aantal proefpersonen:	450
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	27-09-2007
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	NL1040
NTR-old	NTR1073
Ander register	METC Groningen : METc 2007/110
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A