

Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS).

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Thrombus aspiration compared to balloon angioplasty will improve myocardial reperfusion during primary percutaneous coronary intervention.

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

Samenvatting

ID

NL-OMON20434

Bron

Nationaal Trial Register

Verkorte titel

TAPAS

Aandoening

thrombus aspiration; percutaneous coronary intervention: myocardial infarction; myocardial reperfusion

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

Angiographic myocardial blush grade of less than 2.

Toelichting onderzoek

Achtergrond van het onderzoek

Background and objective:

Embolization of atherothrombotic material is common during percutaneous coronary intervention (PCI) in acute myocardial infarction. Adjunctive devices for PCI to protect the microcirculation have been developed. We intend to determine whether aspiration of thrombotic material before stent implantation of the infarct related coronary artery results in improved myocardial perfusion compared with conventional primary PCI.

Study design:

The Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS) is a single-center, prospective, randomized trial with a planned inclusion of 1080 patients with ST elevation myocardial infarction. Patients are assigned to treatment with thrombus aspiration with the 6F Export Aspiration Catheter (Medtronic Corporation, Santa Rosa, California, USA) or to balloon angioplasty before stent implantation in the infarct related artery. The primary endpoint is angiographic myocardial blush grade of less than 2. Secondary endpoints are enzymatic infarct size, ST-segment elevation resolution and persistent ST-segment elevation, post-procedural distal embolization, and Major Adverse Cardiac Events at 30 days and 1 year.

Implications:

If thrombus aspiration significantly improves myocardial perfusion, it will lend support to the use of this treatment as part of the standard approach in patients with acute myocardial infarction.

Doel van het onderzoek

Thrombus aspiration compared to balloon angioplasty will improve myocardial reperfusion during primary percutaneous coronary intervention.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Thrombus aspiration compared to conventional balloon angioplasty during primary percutaneous coronary intervention.

Contactpersonen

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Wetenschappelijk

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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 elevation of more than 0.1 mV in 2 or more leads.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Rescue PCI after thrombolytic therapy;
2. Inability to obtain informed consent;
3. Known existence of a life-threatening disease with a life expectancy of less than 6 months.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2005
Aantal proefpersonen:	1080
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	21-02-2007

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	NL890
NTR-old	NTR914
Ander register	: N/A
ISRCTN	ISRCTN16716833

Resultaten

Samenvatting resultaten

Svilaas T, van der Horst IC, Zijlstra F.

Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS)--study design.

Am Heart J. 2006 Mar;151(3):597.e1-597.e7.