ISRCTN16716833 https://doi.org/10.1186/ISRCTN16716833

Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study

Submission date 07/03/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/03/2007	**Overall study status** Completed	
Last Edited 27/01/2009	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Tone Svilaas

Contact details
University Medical Centre Groningen
Thorax Centre
Department of Cardiology
P.O. Box 30001
Groningen
Netherlands
9700 RB
+31 (0)50 361 0444
t.svilaas@thorax.umcg.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR914

Study information

Scientific Title
Effectiveness of thrombus aspiration compared to balloon angioplasty on myocardial reperfusion during percutaneous coronary intervention in acute myocardial infarction

Acronym
TAPAS

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local ethics committee.

Study design
Randomised, active controlled, parallel group 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
Myocardial infarction

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

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Angiographic myocardial blush grade of less than two

Secondary outcome measures
1. Enzymatic infarct size
2. ST-segment elevation resolution
3. Persistent ST-segment elevation
4. Post-procedural distal embolisation
5. Major adverse cardiac events at 30 days and one year

Overall study start date
01/01/2005

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. A diagnosis of acute myocardial infarction (MI) defined by chest pain suggestive for myocardial ischaemia for at least 30 minutes, with a time from onset of symptoms of less than 12 hours, before hospital admission
2. An electrocardiogram (ECG) with ST-segment elevation of more than 0.1 mV in two or more leads

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1080

Key exclusion criteria
1. Rescue percutaneous coronary intervention (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 six months

Date of first enrolment
01/01/2005

Date of final enrolment

01/01/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Groningen
Groningen
Netherlands
9700 RB

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/#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?
Other publications	study design:	01/03/2006		Yes	No
Results article	thrombus aspiration results:	07/02/2008		Yes	No
Results article	1-year follow-up study results:	07/06/2008		Yes	No
Results article	substudy results	01/03/2009		Yes	No