

Bloodless Reperfusion in Acute Myocardial Infarction

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Treatment of ST-elevation myocardial infarction (STEMI) by means of mechanically reperfusion is often accompanied by reperfusion injury. As pre- and postconditioning in STEMI appears to be ineffective, cardioprotection should occur in parallel (...)

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20782

Bron

NTR

Verkorte titel

BRIAMI PS

Aandoening

Acute Myocardial Infarction

Ondersteuning

Primaire sponsor: Amsterdam University Medical Centers, location VUmc

Overige ondersteuning: Amsterdam University Medical Centers, location VUmc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

30-day major cardiac and cerebral events (MACCE), including peri-procedural complications

Toelichting onderzoek

Achtergrond van het onderzoek

Treatment of ST-elevation myocardial infarction (STEMI) by means of mechanically reperfusion has been shown to be of prognostic relevance. A downside of mechanically reperfusion is that it is often accompanied by reperfusion - or microvascular injury. Recently a promising technique to tackle reperfusion injury has been developed, bloodless reperfusion. In the current trial we will evaluate the safety and feasibility of this technique as well as evaluate intracoronary derived pressure parameters to identify microvascular injury prior to reperfusion in a STEMI population.

Doel van het onderzoek

Treatment of ST-elevation myocardial infarction (STEMI) by means of mechanically reperfusion is often accompanied by reperfusion injury. As pre- and postconditioning in STEMI appears to be ineffective, cardioprotection should occur in parallel (perconditioning) to the sustained coronary occlusion and interact with the distal coronary arterial micro-circulation prior to epicardial restoration of flow. This is known as bloodless reperfusion and constitutes a new therapeutic strategy to tackle reperfusion injury.

Onderzoeksopzet

The technique of bloodless reperfusion and measurement of CWP, IMR, iFR and FFR will be executed during the index procedure, the primary PCI.

CMR will be performed at 2-7 days and 1 month follow-up

Onderzoeksproduct en/of interventie

The bloodless reperfusion technique will be evaluated:

A adequately sized semi-compliant balloon will be inflated at low pressure (2-4atm) proximal to the occlusion. Thereafter a double lumen microcatheter (over-the-wire) will be advanced distal to the occlusion. Coronary wedge pressure (CWP) will be measured with a pressure wire advanced through the microcatheter. Bloodless reperfusion can also be achieved through the micocatheter.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with an acute STEMI are eligible when they meet the following inclusion criteria: Symptom onset < 6 hours, Thrombolysis In Myocardial Infarction (TIMI) 0 flow, and at least 1 intermediate lesion in a non-infarct related artery.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Major exclusion criteria are cardiogenic shock and a history of prior myocardial infarction or coronary artery bypass grafting (CABG).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	0
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48480
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7379
NTR-old	NTR7587

Register

CCMO

OMON

ID

NL68014.029.18

NL-OMON48480

Resultaten