Safety and Efficacy of sonolysis therapy for treatment of microvascular damage after myocardial infarction

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Is application of diagnostic ultrasound and microbubbles prior and immediately after primary PCI to enhance coronary recanalization and reduce microvascular obstruction when combined with normal care consisting of prasugrel, aspirin and heparin...

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

Samenvatting

ID

NL-OMON28497

Bron
NTR

Verkorte titel
ROMIUS

Aandoening

Myocardial infarction
Hartinfarct

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: Philips Medical Imaging

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• Echocardiographic and enzymatic infarct size
• Microvascular obstruction and haemorrhage on MRI measurements

Toelichting onderzoek

Achtergrond van het onderzoek

Currently, primary percutaneous coronary intervention (PCI) is the treatment of choice in STEMI patients, however, its widespread use is hampered by limited availability of specialized facilities and trained staff. Also, peripheral microvascular obstruction often occurs, as part of the microvascular injury pathway. Therefore, there is a need for simpler and low-risk methods for effective recanalization of thrombosed arteries that can be initiated early in the disease process and after initial primary PCI treatment.

In this respect, the application of ultrasound, and ultrasound in combination with thrombolytic agents have been investigated and were found to enhance thrombus dissolution in vitro and in vivo.

We hypothesize that under influence of ultrasound, UCAs enhance dissolution of thrombus in patients with acute ST-elevation myocardial infarction premedicated with regular treatment with prasugrel, aspirin and heparin followed by bivalirudin and furthermore reduce the amount of microvascular obstruction that occurs after primary PCI.

Doel van het onderzoek

Is application of diagnostic ultrasound and microbubbles prior and immediately after primary PCI to enhance coronary recanalization and reduce microvascular obstruction when combined with normal care consisting of prasugrel, aspirin and heparin followed by bivalirudin a safe and feasible method in this patient group?

Onderzoeksopzet

First visit. 6 week follow-up. 6 month follow-up.

Onderzoeksproduct en/of interventie

Patients will be announced by the ambulance. After announcement by the ambulance of a patient with an eligible STEMI the patient will be pre-treated in the ambulance with a loading dose of aspirin 500 mg iv., heparin 5000 IU iv., prasugrel 60mg po.
Upon arrival on the cathlab, after oral informed consent the patient will also receive Definity Microbubbles as part of the immediate ultrasound therapy

To avoid any time delay, informed consent will be obtained orally, prior to primary PCI and bivalirudin infusion. Investigator will try to obtain written informed consent prior to study procedures. In any other case, written informed consent will be given after primary PCI when the patient is in a stable clinical condition.

After informed consent, patients will be treated with ultrasound application with an UCA. To prevent delay of intended clinical treatment, the study procedure is carried out during the preparation for primary PCI as much as possible. The whole study procedure time including preparation is expected to take a maximum of 15 minutes. After PCI, the patient will receive an additional 30 minutes of UCA treatment.

An intravenous line will be inserted, and continuous registration of a 12-lead ECG is obtained. An automatic blood pressure device will record blood pressure every three minutes during the study procedure.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age > 18 years

• Acute onset (< 6 hours)

• Diagnosed with STEMI according to the criteria of the ACC

• Initial oral informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Clinical instability

• Known allergy to ultrasound contrast agents

• Any reason judged by the investigators to hamper inclusion

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2014
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-09-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41625
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4648
NTR-old	NTR4791
CCMO	NL46176.029.14
OMON	NL-OMON41625

Resultaten

Samenvatting resultaten

1 Daffertshofer M, Gass A, Ringleb P, et al. Transcranial low-frequency ultrasound-mediated thrombolysis in brain ischemia: increased risk of hemorrhage with combined ultrasound and tissue plasminogen activator: results of a phase II clinical trial. Stroke 2005 Jul;36(7):1441-6.
2 Scott PA, Frederiksen SM, Kalbfleisch JD, et al. Safety of intravenous thrombolytic use in four emergency departments without acute stroke teams. Acad Emerg Med 2010 Oct;17(10):1062-71.
3 Kramer C, Aguilar MI, Hoffman-Snyder C, et al. Safety and efficacy of ultrasound-enhanced thrombolysis in the treatment of acute middle cerebral artery infarction: a critically appraised topic. Neurologist 2011 Nov;17(6):346-51.

4 Xie F, Lof J, Matsunaga T, et al. Diagnostic ultrasound combined with glycoprotein IIb/IIIa-targeted microbubbles improves microvascular recovery after acute coronary thrombotic occlusions. Circulation 2009 Mar 17;119(10):1378-85.
5 Gibson CM, Cannon CP, Daley WL, et al. TIMI frame count: a quantitative method of assessing coronary artery flow. Circulation 1996 Mar 1;93(5):879-88.
6 Ndrepepa G, Tiroch K, Keta D, et al. Predictive factors and impact of no reflow after primary percutaneous coronary intervention in patients with acute myocardial infarction. Circ Cardiovasc Interv 2010 Feb 1;3(1):27-33.
7 Kloner RA, Ganote CE, Jennings RB. The "no-reflow" phenomenon after temporary coronary occlusion in the dog. J Clin Invest 1974 Dec;54(6):1496-508.
8 Kondo M, Nakano A, Saito D, et al. Assessment of "microvascular no-reflow phenomenon" using technetium-99m macroaggregated albumin scintigraphy in patients with acute myocardial infarction. J Am Coll Cardiol 1998 Oct;32(4):898-903.
9 Cavalcante JL, Collier P, Plana JC, et al. Two-dimensional longitudinal strain assessment in the presence of myocardial contrast agents is only feasible with speckle-tracking after microbubble destruction. J Am Soc Echocardiogr 2012 Dec;25(12):1309-18.
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