Tissue factor pathway inhibitor (TFPI) in patients with lacunar stroke

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28742

Source
NTR

Brief title
N/A

Health condition

Stroke. Lacunar stroke. Cerebral small vessel disease

Sponsors and support

Primary sponsor: University Hospital Maastricht,
PO Box 5800
6202 AZ Maastricht
The Netherlands
Source(s) of monetary or material Support: Netherlands Thrombosis Foundation

Intervention

Outcome measures

Primary outcome

Levels of Tissue factor pathway inhibitor (TFPI) before and after administation of heparin in lacunar stroke patients and healthy controls.

Secondary outcome

N/A

Study description

Background summary

Endothelial dysfunction is thought to play a role in the development of silent white matter lesions (WMH) in patients with a first ever lacunar stroke. Hassan et al 1 demonstrated that several plasma markers of endothelial function were elevated in lacunar stroke patients compared to controls, but surprisingly some markers (TFPI) were lower in lacunar stroke patients with extensive WML. They concluded that this endothelial dysfunction would contribute to a pro-thrombotic state through activation of the extrinsic coagulation pathway. Earlier, we performed a pilot study in 74 patients with a first ever lacunar infarct to determine to what extent patients with lacunar stroke and concomitant WML have evidence of endothelial cell activation, and whether this would lead to activated coagulation in plasma. Patients underwent a brain MRI. WMH were graded according to the modified Fazekas scale2. vWFag, sTM and TFPI were measured using ELISA or immuno-turbidimetric assay. Chi square analysis was used to relate concentration of plasma markers (divided into tertiles) to severity of leukoaraiosis (divided into a dichotome variable). We found high levels of TFPI to be associated with extended WMH (p=0.026), but sTM and vWF were divided equal between the two groups. We concluded that higher levels of TFPI in lacunar stroke patients with extensive WML could suggest endothelial dysfunction, the lack of difference in plasma levels of vWF and sTM makes this hypothesis unlikely. In the current study, we want to further evaluate the role of TFPI (truncated and full-length) in lacunar stroke patients, by evaluating the release of TFPI by the endothelium after injection of IV heparin.

Study objective

1. Is the release of TFPI by endothelium after admission of heparin different between lacunar stroke patient and healthy controls?

2. Is the release of TFPI by endothelium after admission of heparin different between lacunar stroke patients with or without concomitant ischemic white matter lesions?

Study design

The first sample of blood is drawn several minutes before administration of heparin.

The second and last sample, 15 minutes after administration of heparin.

Intervention

Single intravenous dose of 7500 IU of heparin, preceded and followed by withdrawal of 30 ml of blood.

Contacts

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Eligibility criteria

Inclusion criteria

Patients:

1. First ever lacunar stroke patient (>18 years old)

2. Informed consent.

3. Absent of white matter hyperintensities OR extensive white matter hyperintensities on MR-scanning of the brain.

Controls:

1. Healthy controls (>18 years old)

Exclusion criteria

Patients:

1. Use of oral anticoagulants, heparin (derivates) of substances with ulcerogenic action (adrenal gland hormones or anti-rheumatic medication).

2. Allergy for heparin.

3. Arterial or venous thrombosis in the past three months.

4. History of hemorrhage in urogenital tract, digestive tract or intracerebral.

5. Personal history or family history of hemorrhagic diathesis

6. Malignant hypertension

7. Brain microbleeds on Gradient-echo of FFE - images (MRI)

Controls:

1. Same as patients and,

2. History of cardiovascular events (stroke, myocardial infarction or periphery artery disease)

3. Known cardiovascular risk factors (hypertension, diabetes mellitus).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	30
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 31866
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1334
NTR-old	NTR1392
CCMO	NL23829.068.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON31866

Study results

Summary results

N/A