Potential value of a Brain-type fatty acid-binding protein test in suspected TIA

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To investigate if the detection of B-FABP is possible in the blood of TIA patients (between 6 and 72 hours after the onset of symptoms) and referred by their general practitioner to the outpatient TIA-clinic of the UMC Utrecht or Diakonessenhuis...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON33168

Source
ToetsingOnline

Brief title
B-FABP in TIA

Condition

- Central nervous system vascular disorders

Synonym
Transient Ischaemic Attack (TIA)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: B-FABP, biomarker, bloodtest, TIA

Outcome measures

Primary outcome

Level of B-FABP in the blood of the patiënts

Final diagnosis stated by the neurologist

Secondary outcome

n.v.t.

Study description

Background summary

It is difficult to diagnose a patient with a history (and only sometimes signs and symptoms) suggestive of a minor stroke or transient ischaemic attack (TIA). No simple diagnostic test with acceptable positive or negative value is available There is no diagnostic test available. Recent studies underline the fact that TIA is a medical emergency and adequate targeted treatment of these patients reduces disability and costs.(1) Urgent treatment of patients suspected of TIA with existing preventive treatment could reduce the risk of recurrent stroke by 80-90%.(2) However, many patients are not correctly diagnosed in primary care.
B-FABP is a relatively new biomarker which could be used in the rapid detection of brain injury. B-FABP is specific for brain damage and detectable within a few hours after the event.(4) Pelsers et al. showed that B-FABP is detectable in patients with ischaemic stroke and proved to be useful also for the detection of minor damage.(4,5)
We are planning a large trial to evaluate the value of a B-FABP blood test in patients suspected with TIA in addition to clinical findings. In this pilot study we want to test feasibility of the procedures and to investigate if B-FABP is detectable in the blood of TIA patients more often than in patients without TIA.

Study objective

To investigate if the detection of B-FABP is possible in the blood of TIA patients (between 6 and 72 hours after the onset of symptoms) and referred by

their general practitioner to the outpatient TIA-clinic of the UMC Utrecht or Diakonessenhuis Utrecht.

Study design

This is a cross sectional pilot study, designed to evaluate B-FABP-values in the blood of TIA patients. During 3 months we include 50 patients suspected of a TIA and visiting the outpatient TIA clinic of the UMC Utrecht or Diakonessenhuis Utrecht. between 6 and 72 hours after onset of symptoms.

Flowchart of the investigation and the TIA clinic diagnostic workup see the protocol on page 7

With the help of the results, the investigating neurologists will state the final diagnosis, TIA or no TIA, being the reference test.
For our research, one extra 20 ml tube of blood will be collected and the patient fills out a questionnaire with some questions about awareness, signs, symptoms and delay before referral.

Study burden and risks

We will take one extra sample of 20 ml blood from the patients. It might be necessary to perform an extra venapuncture because of logistic reasons. There will be no risk for the patient, nor is any physical or psychological discomfort by participating in this investigation suspected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with symptoms suspected of TIA lasting less than 24 hours, who arrive at the out-patiënt TIA clinic between 3 and 72 hours from symptom onset.

Exclusion criteria

TIA symptom onset >72 hours.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2010
Enrollment:	50

Type:	Actual

Ethics review

Approved WMO Date:	22-09-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL27090.041.09