The Dutch Acute Stroke Trial: prediction of outcome with CT perfusion and CT angiography.

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To assess the additional prognostic value of combined CTP and CTA parameters to baseline patient criteria and plain CT. Secondary objective is to subsequently use the best CTP and CTA indicators of outcome of infarct in a prediction model for...

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

Summary

ID

NL-OMON36955

Source
ToetsingOnline

Brief title
DUST

Condition

- Central nervous system vascular disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
ischemic infarct, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: cerebral ischemia, CT perfusion, imaging, outcome assessment

Outcome measures

Primary outcome

primary outcome measures will be 90 day outcome measured by modified Rankin

Scale (mRS).

Secondary outcome

Day 3 outcome (NIHSS and mRS) or earlier at discharge.

Vessel recanalization on CTA.

Final infarct size.

Asymptomatic and symptomatic hemorrhage on CT.

Study description

Background summary

Prediction of outcome is necessary to make the right therapeutic choice in patients with acute ischemic stroke. Outcome is unpredictable on plain CT and clinical information alone. CT perfusion and angiography are easily accessible and can probably predict outcome and forecast the expected chance of benefit or harm of thrombolysis or thrombectomy. This essential first step can only be taken now before new intervention techniques are implemented.

Study objective

To assess the additional prognostic value of combined CTP and CTA parameters to baseline patient criteria and plain CT. Secondary objective is to subsequently use the best CTP and CTA indicators of outcome of infarct in a prediction model for improving choice of therapy.

Study design

Prospective multi-centre cohort study.

Study burden and risks

The burden consists of an extra plain CT brain, a CT perfusion and a CT angiography 3 days after the onset of symptoms and after 90 days a questionaire will be performed by phone. The CT scans will take 10 minutes (30 minutes with transport and transfer to table) and the questionaire around 15 minutes. The risks involved are radiation and contrast reactions. Both risks are small and acceptable considering the gravity of the deficits after a stroke. The inclusion of incapacitated patients is justified because this is directly related to the disease and especially this patient group is likely to benefit from a better prediction model for therapeutic choice.

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

Acute neurological deficit caused by cerebral ischemia within 9 hours of onset.
No known contraindictations against intravenous contrast.
Informed consent.

Exclusion criteria

Another diagnosis such as intracerebral hemorrhage, subarachnoid hemorrhage or tumor.
Known contrast allergy or renal failure.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-05-2009
Enrollment:	1500
Type:	Actual

Ethics review

Approved WMO Date:	03-03-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-10-2009

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-07-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-05-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-07-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-09-2011
Application type:	Amendment
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	NL25625.041.08