Time Resolved Angiography in Cerebrovascular Shunts (TRACS)

Published: 22-04-2010
Last updated: 04-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON39157

Source
ToetsingOnline

Brief title
TRACS

Condition

- Vascular disorders NEC

Synonym
Arteriovenous malformations and dural arteriovenous fistulas

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,additional funding is being sought.

Intervention

Keyword: 4D-CTA, AVM, Brain, DAVF

Outcome measures

Primary outcome

With regard to each AVM or DAVF characteristic the sensitivity, specificity, positive and negative predictive power of 4D-CTA will be calculated when compared to the gold standard (CA). Also, the ability of 4D-CTA to correctly classify the lesion and to determine an appropriate treatment strategy will be compared to CA.

Lesion analysis

All CA and 4D-CTA images will be reviewed by two neuro-interventionalists and a neurosurgeon experienced in such evaluations. These reviewers will be blind for patient identity and the findings from the other imaging modality.
The reviewers will assess the presence or absence of an AVM or DAVF, it*s classification and a number of clinically relevant characteristics based on a predefined score sheet.

Treatment strategy

For all patients, the reviewers will be asked to determine a treatment strategy based on the CA and 4D-CTA images, respectively. In addition, the reviewers will rate their degree of confidence concerning the chosen strategy based on a 5-point Likert scale (absolutely certain, sufficiently certain, ambiguous, insufficiently certain, absolutely uncertain).

After reviewing the 4D-CTA images, each reviewer will be asked to address

whether additional CA is expected to be of additional value.

Secondary outcome

not applicable

Study description

Background summary

The gold standard for intracranial vascular imaging has traditionally been catheter angiography (CA), offering high spatial and temporal resolution. In recent years, less invasive angiographic techniques, e.g. magnetic resonance angiography (MRA) and computed tomographic angiography (CTA), have replaced CA for many clinical indications. Aside from being less time consuming and less expensive, these alternatives carry smaller procedural risks, as they do not require arterial catheterization. In the diagnosis of cerebral arterio-venous shunting lesions, i.e. arterio-venous malformations (AVMs) or dural arterio-venous fistulae (DAVFs), it is key to demonstrate the actual shunting by showing premature filling of a vein. For this purpose, CTA and MRA have thusfar not been able to replace CA, as these are essentially 'vessel-cast' techniques lacking important dynamic information.
The development of CT scanning equipment with 320 parallel detector arrays has recently enabled non-invasive dynamic visualization of the entire cranial circulation, maintaining spatial resolution (4D-CTA). Our initial patient data suggest its value in the diagnosis and classification of cerebral arterio-venous shunting lesions. Especially in DAVFs, lesion classification correlates to natural history (i.e. the risk of intracranial hemorrhage) and determines, to a large extent, which treatment strategy should be chosen.

Study objective

The aim of this project is to assess whether 4D-CTA can generate 3D cranial image data sets with sufficient spatial and temporal resolution to enable its use as a diagnostic tool in cerebrovascular pathology and physiology such as arteriovenous shunting lesions and hence to enable a change in routine clinical

practice, replacing CA and the risks it carries.

Hypothesis 1:
The negative predictive value of 4D-CTA for a cranial arterio-venous shunting lesion is sufficient to rule out such a lesion with a reasonable level of certainty.

Hypothesis 2:
When 4D-CTA detects a cranial arterio-venous shunting lesion, the detail is sufficient for lesion classification and determination of treatment strategy.

Our study objective is to show the validity of the hypotheses, which would indicate the value of 4D-CTA in the diagnostic work-up of patients suspected to suffer from a cranial AV shunt.

Study design

Patients will be enrolled at the Leiden University Medical Centre (Leiden, the Netherlands) as well as several international centers. We intend to cooperate with at least 3 other centers to increase patient inclusion: Toronto (Canada, co-investigator: K.G. terBrugge), Ottawa (Canada, co-investigator: M. Santos) and Bangkok (Thailand, co-investigator: S. Pongpech). These centers are specialized in neurovascular disorders, have the necessary equipment and CTA-expertise and have indicated willingness to cooperate. Patients will be recruited prior to CA imaging, either during their visit to the vascular clinic or upon admission. After signing an informed consent, each patient will undergo 4D-CTA imaging within a week of undergoing CA imaging. To protect patient identity, all imaging used for the purpose of this study will be stored and presented on the basis of an assigned study ID number.

Imaging parameters will be compared in all patients undergoing both CA and 4D-CTA imaging. These parameters will include radiation burden, contrast burden, time needed to perform the examination the necessary post-processing, spatial resolution, temporal resolution and diagnostic value. The latter will be assessed by having two observers score their ability to determine diagnosis, classification, clinically relevant lesion details and proposed treatment strategy.

Timeframe
The expected timeframe for the study is expected to be three years.
Yearly, our center typically finds 10 new DAVF patients and 15 AVM patients. To diagnose these, we need to perform imaging in approx. 20 patients suspected of a DAVF and 20 patients suspected of an AVM. We intend to cooperate with at least 3 other centers to increase patient inclusion.
We expect the numbers in these centers to be either equal to ours or higher. Thus, yearly, we expect to image a combined total of 80 patients to find 40 DAVFs and another 80 patients to find 60 AVMs. If 75% of patients comply with

our inclusion and exclusion criteria, 120 patients would be included with 75 positive findings (30 DAVFs and 45 AVMs). In two study years the total yield would be 240 included patients with 150 positive findings. We believe this to be an adequate number. A third year will be necessary to start-up and perform post-close-out analysis.

Study burden and risks

There are two types of direct benefits to be gained for the patient by participating. Firstly, the information acquired during a 4D-CTA examination allows for the reconstruction of traditional axial cranial CT images and CT perfusion maps, which may yield findings relevant to treatment planning. Secondly, if the lesion is indeed demonstrated by 4D-CTA, follow-up imaging can also consist of 4D-CTA rather than CA, thus reducing the number of invasive procedures the patient needs to endure.

Benefits for this patient group in the future are related to a number of definite drawbacks associated with CA, when compared to 4D-CTA. CA is an invasive procedure with a high incidence of silent embolic events and a small risk of transient or permanent neurological deterioration. The arterial puncture and the post-procedural immobilization (at least 4 hours intramural) to prevent arterial bleeding are associated with patient discomfort. Aside from the patient, the radiologist and supportive staff are also exposed to ionizing radiation. And even though post-processing of a 4D-CTA may take the CT operator up to 30 minutes, a CA is considerably more time consuming for the radiologist and the patient.
Due to its drawbacks, CA has been replaced by non-invasive alternatives for a number of clinical questions regarding extracranial vascular pathology. If we show the novel technique of 4D-CTA to be of sufficient diagnostic yield in patients with an AVM or DAVF, this would result in a reduction of expenses, time consumption and morbidity related to the diagnostic work-up of such patients. Furthermore, such results would allow CA to be replaced by 4D-CTA whenever repeat imaging is requested during follow-up.
On the other hand, if we show 4D-CTA to be insufficient to replace CA, this will demonstrate the limitations of this new technique and prevent its unjustified use in this patient category.

Patients participating in this study will be subjected to a single extra examination, i.e. 4D-CTA, thus exposing them to an extra dose of contrast material and radiation. The burden of contrast material will be comparable to that involved with a routine cranial CT examination. The radiation burden will be slightly higher than that of a routine cranial CT examination (approx. 4 mSv).
Specific CTA risks:
- Contrast Induced Nephropathy: in non-selected patients the incidence of temporary hemodialysis is 0.2%. This is even lower when patients with preexisting renal problems are excluded (as in our study).

- Allergic reactions to iodinized contrast media can occur but are usually mild. In case of more severe reactions, qualified medical staff is always present on site to intervene if necessary.
- Radiation hazard is far less than 1% with this amount (about 5.1 mSv) additional radiation dosage.

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

Patient age 18 years or older
Clinical suspicion of AVM or DAVF
Diagnostic catheter angiography requested by treating physician

Exclusion criteria

Absence of informed consent
Diabetes mellitus
Chronic kidney disease (baseline eGFR < 50 ml/min)

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):	01-07-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	22-04-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	21-05-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL30012.058.09