The value of CT angiography in patients with acute severe headache; a prospective study

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Determining the diagnostic value of CTA in patients with acute headache and normal neurological examination and head CT by performing a prospective study. Charting patient characteristics in order to more purposefully apply the CTA and avoid...

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

Summary

ID

NL-OMON43701

Source
ToetsingOnline

Brief title
CT angiography in acute headache

Condition

- Central nervous system vascular disorders

Synonym
acute severe headache, thunderclap headache

Research involving
Human

Sponsors and support

Primary sponsor: Neurologie
Source(s) of monetary or material Support: Jacobus stichting

Intervention

Keyword: CT angiography, headache, prospective

Outcome measures

Primary outcome

- The number of intracranial abnormalities in this group found by CTA.

- All CTA's will be evaluated by experienced neuro-radiologists

- The presence of SAH, unruptured aneurysms, cerebral venous thrombosis,

carotid or vertrebral arterial dissection and reversible vasocontstriction

syndrome will be monitored.

- Headache and patient characteristics will be determined in order to apply CTA

more purposefully in the future

- The number of changed diagnosis due to CTA performance will ben monitored.

Secondary outcome

N/A

Study description

Background summary

Acute headache may be an isolated symptom of subarchnoid hemorraghe (SAH), cerebral venouw thrombosis (CVT), reversible cerebral vasoconstriciont syndrome (RCVS) or carotid dissection. The are serious conditions with high morbidity and mortality. If a patient presents with acute headache routinely a standard head CT is performed. If this CT is performed within 6 hours after the start of the headache, and is evaluated by an experienced neuro-radiologist a SAH is sufficiently excluded. If this scan is performed after 6 hours sensitivity drops and a lumbar puncture is still mandatory to exclude SAH. However in using this method diagnosis like CVT, RCVS or dissection may be missed. For this reason CT angiography (CTA) of the cerebral arteries is increasingly used in the MCH and LUMC to exclude both arterial en venous pathology. In current clinical practice 80% of patients between the hospitals receive a CTA, however

diagnostic value has never been prospectively researched in this patient group. Also reasons for making this scan vary between neurologist without clear reasons. This practice is objectionable as complications due to scanning may occur:
- The iodine contrast that is given for this scan may cause nefropathie in a small group of patients. Varying percentages have been cited from <1% in patients without risk factors to 11% in higer risk patients. The risks are significantly reduced by the use of a local contrast nefropathy protocol which has been proven to reduce the risk of contrast nefropathie to 1.4%.
- Secondly there is a risk of contrast allergies.
- Finally radiation exposure is raised from 2mSV for a standard head CT tot an additional 3.5mSv for the CTA. Radiation may be reduced by immediate performance of the CTA or a more sensible use of CTA in a selected group of patients.
The diagnostic value of CTA in this patient group has not been proven unequivocally. Several longitudinal studies have followed patients with acute, severe headache after a normal head CT and lumbar puncture and found no risk of raised SAH. however follow times varied greatly and as CTA was not performed other diagnoses may have been overseen. A recent study shows 6.6% vascular abnormalities in this patient group after CTA. In recently published data from our own centre we found 19% vascular abnormlities in patients with a normal head CT and lumbar puncture. Both percentage are significantly higher than may be expected in the general population.
As there a re no prospective studies regarding this subject, we hope that this current study may shed some light on the value of CTA in patients with acute, severe headache and a normal neurological examination and head CT. We hope to be able to make a better selection for scanning based on patient characteristics, thus reducing unecessary diagnostics

Study objective

Determining the diagnostic value of CTA in patients with acute headache and normal neurological examination and head CT by performing a prospective study. Charting patient characteristics in order to more purposefully apply the CTA and avoid excessive diagnostics.

Study design

The study will be a prospetive diagnostic study in two hospitals with neuro-vascular expertise: the MC Haaglanden en LUMC. We will prspectively include all patients with acute severe headache who present to the emergency room and a normal neurological examination. In the current clinical practive the patients undergo a standard head CT and if necessary an lumbar puncture to exclude hemorraghe. Between the two hospitals 80% receive a CTA. In the remaining group the reasons for not performing a CTA is unclear as is the possible diagnostic yield. In order to avoid indication bias we wish to als

perform CTA on the remaining 20% of patients also.
Patients will be included and asked for consent by the treating physician. For all patients it will be noted when a phycisian decides to make a CTA or not and why. The patients in whom the treating phycisian does not see the indication for CTA, informed consent will be obtained to perform CTA for study purposes. Should there be a risk of contrast nefropathie patients will be prepared according to the local IV contrast nefropathy risk protocol. If there are absolute contra indications patient will be excluded, but data will be noted for possible follow up and to evaluate the occurence of contra-indications. Headache charateristics will be inventoried. Differential diagnosis before and after CTA will be noted to evaluate changes due to CTA performance.

Study burden and risks

In current clinical practice 80% of pateints with acute severe headache receive CTA in their diagnostic follow up. The diagnostic yield and value of this practice is unknown. In this study a further 20% of patients will receive a CTA. As we hope to include 200 patients, this will amount to 40 patients. Participation in this study will subject these patients to an added radiation exposure of 3.5mSv, and also added exposure to iodine contrast fluid via intravenous injection.
All patients will be subjected to a questionaire lasting approximately 30 minutes. After a year patients will be contacted again for follow up via a telephone questionaire which will last 10 minutes.
The aim of this study is to more purposefully apply CTA and thus reduce these risks for future patients. Should CTA prove usefull in this patient group, then standard head CT may be dismissed as interval diagnostic tool. This would reduce radiation exposure with 2mSv to an only added 1.5 mSv. As this may be applied to a selected group based on study result overall exposure may be reduced in a group in which 80% now receive both standard head CT and CTA (total 5.5mSv).
Risk of contrast nefropathie will be evaluated according to local nefropathie protocol and patients will be treated accordingly.
Should pathology be found in the course of this study than patients will receive necessary follow up and treatment.

Contacts

Public
Selecteer

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Scientific
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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 severe headache, with a maximum within five minute, lasting longer than 1 hour.
- Worst headache ever experienced
- Normal neurological examination
- Normal standard head CT, without lumbar puicture if performed <6 hours of start of headache and evaluated by experienced neuro-radiologist.
- If standard head CT performed >6 hours a lumbar puncture with normal chemistry and opening pressure.

Exclusion criteria

- Abnormalities on standard head CT; hemorraghe, recent ischaemia, tumor.
- focal abnormalities at neurological examination
- Abnormalities in CSF chemistry of opening pressure, if lumbar puncture is performed.
- Poor of bad kindey function,defined by an eGFR<60ml/min
- Known contrast allergy

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):	06-04-2016
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	30-06-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	16-12-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO

Date:	21-09-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	10-08-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL51182.098.15