Contrast enhanced ultrasound to measure cerebral blood flow

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

Summary

ID

NL-OMON42396

Source
ToetsingOnline

Brief title
Contrast enhanced ultrasound to measure cerebral blood flow

Condition

- Central nervous system vascular disorders

Synonym
acute brain injury, acute cerebral ischemia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cerebral blood flow, microbubbles, transcranial Doppler, ultrasound

Outcome measures

Primary outcome

Main study parameter is the reproducibility of the CEUS bolus kinetics and the flash-replenishment method. A difference between the measurements of more than 10% is considered to imply poor reproducibility. As a control, the reproducibility of measurement of the flow velocity in the ipsilateral middle cerebral artery will be assessed. .

Secondary outcome

Secondary study parameters are 1) Correlation between the bolus kinetics approach and the flash-replenishment method and 2) Comparison of the CEUS bolus technique with transcranial Doppler (at 2 different levels of cerebral blood flow

Study description

Background summary

The primary goal of neurocritical care is the prevention and management of secondary cerebral damage. Cerebral ischemia is considered as a common final pathway in secondary brain injury and generally occurs when the balance between delivery and consumption of oxygen and nutrients in the brain is disturbed. Monitoring the cerebral blood flow (CBF) is essential in patients with acute brain injury, however, no bedside technique is available for use in critically ill patients. Contrast enhanced ultrasound (CEUS) is an established technique that allows real-time assessment of focal lesions in the brain and for assessment of neurovascular lesion in patients with sroke. Ultrasound is an attractive technique because it is non-invasive, has a high temporal resolution and can be used at the bedside. With the use of ultrasound contrast agents (UCAs) the low level of acoustic intensity due to the ultrasound absorption of

the skull can be overcome, thus improving the signal-to-noise ratio. No quantitative technique has been developed yet in the CEUS technology.

Study objective

This protocol is a first pilot study to determine both feasibility and reproducibility of CEUS in the quantification of CBF. Aim of the current study is to determine the reproducibility of CEUS in quantification of cerebral blood flow, compared to transcranial Doppler at normal and impaired CBF. In addition, differences in quantification using a bolus technique and the refill kinetics will be studied.

Study design

Observational study

Study burden and risks

The burden of acute brain injury is enormous, both from a clinical and economical perspective. Since adequate supply of blood containing oxygen and glucose is crucial for the recovery and survival of brain tissue, monitoring the cerebral blood flow (CBF) is an essential part of neurocritical care. However, easy, non-invasive and reliable direct bedside monitoring of the CBF is not feasible at this moment in the ICU. Development of such a method is very likely to improve the quality of care in patients with acute brain injury since early detection of reduced cerebral blood flow provides the opportunity of intervention to prevent ischemia. In addition, the effect of therapeutic intervention to improve cerebral blood flow can be assessed with adaption of the intervention if necessary.
The burden of the study procedures consists of the time investment related to the screening procedure and 1 visit to the hospital, with a total time of hospitalisation of approximately 3 * hours. All subjects will visit the hospital for a screening visit in which a medical interview, physical examination, ECG recording and transcranial Doppler will be performed. For the bloodflow measurements, transcranial ultrasound and Doppler will be performed, which is not painful and does not induce any discomfort. All subjects will receive a standard venous canula (18G) in the left or right fossa cubiti. Mild hyperventilation is performed by the subject itself, and is generally well tolerated in previous experiments in our department.
The use of ultrasound and transcranial Doppler for the measurement of flow is without any risk. The ultrasound contrast agent SonoVue is used in general clinical practice (mainly by cardiologists and oncologists) and has an excellent safety profile. Mild, temporary side effects have been reported, such as nausea, flushing, pruritus and backache. The risk of serious adverse events caused by the use of SonoVue is estimated at 0.0086%, of which none were fatal. Possible adverse effects associated with mild hyperventilation are easily

managed by cessation of hyperventilation.
Our research population consists of young male and female volunteers that are from a young age group (18-35 years) and in general good health. We chose to select this young and healthy population to avoid the risks of SonoVue even further.
Privacy of the volunteers is guarded by handling and storing the research data using the guidelines of good clinical practice (GCP) as recorded in our data management plan. There is no risk of social stigmatization. There is no risk for exclusion from health insurance.
In light of the abovementioned potential issues of concern, we assess the possible damage for our volunteers in the present study to be `light`. We assess the possibility that this will occur as `small`. Therefore, in line with the guidelines provided bij the NFU (Dutch Federation of University Medical Centres), the risk classification for this study is `negligible risk`.

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

Healthy men or women of 18-35 years old

Exclusion criteria

Hypersensitivity to the active substance(s) or to any of the excipients in SonoVue
Right-to-left shunt cardiac shunt
Severe pulmonary hypertension (pulmonary artery pressure >90 mmHg)
Uncontrolled systemic hypertension
Pregnancy
Lactation
Participation in another clinical trial within 3 months prior to the experimental day.
History, signs, or symptoms of cardiovascular disease or pulmonary disease
History, signs or symptoms of neurological disease
History of hyperventilation

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):	24-06-2015
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	23-04-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-06-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL52854.091.15