Autoregulation of cerebral blood flow in patients after cardiac arrest

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Primary Objective: to determine the strength of the dynamic autoregulation of patients after cardiac arrest during the post cardiac arrest syndrome. Secondary Objectives:to observe the natural course of the autoregulation during the first year after...

Ethical review	Approved WMO
Status	Pending
Health condition type	Encephalopathies
Study type	Observational non invasive

Summary

ID

NL-OMON42261

Source
ToetsingOnline

Brief title
Autoregulation after cardiac arrest

Condition

- Encephalopathies

Synonym
ischemic brain injury, postanoxic encephalopathy

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: autoregulation, cardiac arrest, cerebral blood flow

Outcome measures

Primary outcome

State of dynamic autoregulation as measured by the THRT, defined as impaired

(THRR <= 1.09) or normal (THRR > 1.09) during the post-cardiac arrest syndrome.

Secondary outcome

Dynamic autoregulation using transfer function analysis of the transcranial

Doppler signal

Dynamic autoregulation using transfer function analysis of the NIRS signal

Study description

Background summary

Out-of-hospital cardiac arrest (OHCA) is the leading cause of death in industrialized countries. Rates of survival with favourable neurological outcome are low. Although in the past decades more patients have a return of spontaneous circulation (ROSC), overall prognosis has not substantially improved and only a minority of patients survive with a favorable neurological recovery. The poor prognosis of patients after ROSC is related to the development of the so called post-cardiac arrest syndrome. Crucial in the ICU treatment after cardiac arrest is creating an optimal environment for cerebral recovery and limiting the secondary brain damage occurring during the post-cardiac arrest syndrome. Modulating these pathophysiological processes may prevent secondary neurological damage and possibly improve the survival rate.
The cerebral blood flow (CBF) is mainly controlled by the brain itself by metabolic activity, cerebrovascular reactivity and pressure autoregulation. After cardiac arrest, ROSC does not automatically restore normal cerebral circulation. The amount of brain damage after cardiac arrest strongly depends on the recovery of the cerebral circulation. The state of the autoregulation in patients after cardiac arrest is not well known.
The optimal target blood pressure in patients after cardiac arrest is highly individually determined and the level of autoregulation will play a key role in determining this optimal target pressure.

Aim of the proposed study is to take the first step into individualized optimal blood pressure targeting in patients after cardiac arrest. Determination of the state autoregulation during the post cardiac arrest syndrome is an essential step in this process, as it determines the effect of blood pressure on cerebral blood flow.

Study objective

Primary Objective:
to determine the strength of the dynamic autoregulation of patients after cardiac arrest during the post cardiac arrest syndrome.

Secondary Objectives:
to observe the natural course of the autoregulation during the first year after the arrest and to compare different techniques of dynamic cerebral autoregulation

Study design

Observational study

Study burden and risks

Due to the nature of the disease (coma after cardiac arrest) the patients will be at least temporarily incapacitated. Intensive cerebral monitoring of these patients is considered as part of standard patient care. The different techniques of measurement of cerebral autoregulation are well established and validated. Currently, these techniques are being introduced into standard patient care, because they provide valuable and relevant clinical information. The tests proposed in this study (THRT and change in the position of the bed) are non-invasive, well-tolerated, with a minimal burden or risk for the patient, who is established in advance by physical examination and ultrasound that there are no abnormalities in the carotid artery.The tests do not influence standard patient care in any way.

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

1. Comatose (Glasgow coma scale <= 8) after return of spontaneous circulation, after cardiac arrest
2. Presumed cardiac origin of the arrest

Exclusion criteria

1. pregnancy;
2. thrombolytic therapy;
3. refractory cardiogenic shock;
4. life expectancy of < 24 hours;
5. history of chronic atrial fibrillation;
6. intra aortic balloonpump;
7. known carotid artery stenosis, or signs of carotid artery stenosis on physical examination or ultrasound

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2015
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-03-2015
Application type:	First submission
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	NL52259.091.15