The effect of autonomic nervous system activity on the development of systemic immunosuppression and nosocomial infection in critically ill patients with brain injury

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To examine the effect of parasympathetic and sympathetic nervous system activity on the systemic innate immune response and the incidence of nosocomial infections in patients with vascular or traumatic brain injury. A second objective is to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON37393

Source
ToetsingOnline

Brief title
Brain injury-mediated immunosuppression

Condition

- Bacterial infectious disorders
- Central nervous system vascular disorders

Synonym
infection contracted in the hospital, nosocomial infection

Research involving
Human

Sponsors and support

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

Intervention

Keyword: autonomic nerve activity, brain injury, immunosuppression, nosocomial infection

Outcome measures

Primary outcome

nosocomial infection

Secondary outcome

heart rate variability, markers of sympathetic, inflammatory and coagulation

response, 28- and 60-day mortality, ventilator-free days, length of ICU/CMC

stay and hospital stay.

Study description

Background summary

Patients with vascular or traumatic brain injury often develop secondary nosocomial infection, in particular in the first few days following the insult, leading to enhanced morbidity and mortality. This phenomenon may be due to immune suppression following brain injury.

Study objective

To examine the effect of parasympathetic and sympathetic nervous system activity on the systemic innate immune response and the incidence of nosocomial infections in patients with vascular or traumatic brain injury.
A second objective is to determine the mechanism of brain injury mediated immunosuppression.

Study design

Two-site prospective observational case-control study

Study burden and risks

There is no potential benefit for the research participants. The risk to incapacitated adults is no greater than that to brain injury patients able to give consent, and the study specifically pertains to this group of more severely brain injured patients. We expect the study to cause a minimum of discomfort to participants.

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

Patients with ischemic or hemorrhagic cerebrovascular accident or patients with traumatic brain injury, requiring admission and monitoring on the Intensive Care Unti or Central

Medium Care

Exclusion criteria

Moribund patients
Patients requiring an emergency thoracotomy
Known pregnancy;
Burns or inhalation injury;
Patients who received cardiopulmonary resuscitation with chest compressions (> 5 consecutive minutes) before ICU/CMC arrival
Patients with known do-not-resuscitate order prior to inclusion
Patients receiving immunosuppressive medication
Patients enrolled in a concurrent ongoing interventional, randomized clinical trial

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2013
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	04-07-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL40155.018.12