Neuroinflammation in sepsis encephalopathy: the NINEVEH-study

Published: 27-10-2015
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Primary objective is to assess in vivo neuroinflammation quantitatively in patients with sepsis. Secondary objective is to study whether differences in in vivo neuroinflammation are related to long term cognitive outcomes.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ancillary infectious topics
Study type	Observational non invasive

Summary

ID

NL-OMON42342

Source
ToetsingOnline

Brief title
The NINEVEH-study

Condition

- Ancillary infectious topics
- Encephalopathies

Synonym
'sepsis associated delirium'; post-sepsis syndrome

Research involving
Human

Sponsors and support

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

Intervention

Keyword: neuroinflammation, PET, sepsis, TSPO

Outcome measures

Primary outcome

PET-CT tracer uptake

Secondary outcome

Neuropsychological outcomes

Study description

Background summary

Following a hospitalization for an infection (e.g. sepsis), patients have significantly increased risk for developing cognitive decline. In addition, neuroinflammation plays an important role in the pathogenesis of neurodegenerative disease. Systemic inflammation, as occurs during infections, can induce neuroinflammation. It is hypothesized that neuroinflammation during sepsis is an important factor to the trajectory of cognitive decline in patients with sepsis.

Study objective

Primary objective is to assess in vivo neuroinflammation quantitatively in patients with sepsis.
Secondary objective is to study whether differences in in vivo neuroinflammation are related to long term cognitive outcomes.

Study design

Observational study

Study burden and risks

* Patients will undergo a single PET and MRI scan of the brain. The load of ionizing radiation of the PET-CT is approximately 10 mSv; comparable to a normal abdominal CT-scan. This will be performed 1-2 weeks after sepsis onset.
* One blood sampling will be performed to correct for individual affinity to

the PET tracer.
* Patient will undergo clinical examinations during the hospital admission, including cognitive screening.
* At 3, 6 and 12 months, follow-up examination will be performed with the focus on neuropsychological testing.

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

Sepsis;
Age >50 years

Exclusion criteria

* Pregnancy or wish to become pregnant within 2 weeks after PET-CT scan;
* Contra-indication to undergo a CT or MRI scan, including claustrophobia;
* Unstable hemodynamics or respiration that contra-indicate transport and undergoing PET/MRI imaging;
* Other causes not related to sepsis that sufficiently explain (relation in time) the onset of delirium such as newly onset severe kidney or liver failure, or severe electrolyte disturbances, severe hypoglycaemia;
* Delirium coinciding with start of medications known to increase the risk of development of delirium. This will be judged by the delirium expert: e.g. neurologist, geriatrician, or senior delirium researcher (e.g. based on the type of drug known to trigger delirium and the temporal relationship between start of the medication and onset of delirium);
* Presence of delirium before onset of infection;
* Age < 50 years;
* Moribund patients or patients on palliative care;
* Brain or spinal surgery within the last 3 months;
* Meningitis or brain infection within the 6 months;
* Pre-existing cognitive impairment interfering with the ability to understand informational material about this research project;
* Presence of a CSF catheter or shunt;
* Patients with known brain tumours;
* Patients with brain injury (e.g. acute stroke, brain trauma, or subarachnoid haemorrhage) within the last 3 months;
* Chronic (>6 weeks) use of immunosuppressive agents;
* Concomitant diseases resulting in severe immunosuppression (e.g. HIV);
* Chronic use of neuroleptics, defined as pre-hospital use;
* Patients that do not speak Dutch or have disabilities that prevent accurate delirium diagnosis;
* Analphabetic patients;

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-05-2016
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	N,N-diethyl-2-(2-(4-(2-fluoroethoxy)phenyl)-5,7-dimethylpyrazolo[1,5-□]pyrimidin-3-yl)acetamide
Generic name:	14F-DPA-714

Ethics review

Approved WMO Date:	27-10-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-12-2015
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
EudraCT	EUCTR2015-003698-13-NL
CCMO	NL54775.091.15