INSULIN RESISTANCE AND ANEURYSMAL SUBARACHNOID HEMORRHAGE

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Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON31754

Source
ToetsingOnline

Brief title
IR and SAH

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Central nervous system vascular disorders
- Aneurysms and artery dissections

Synonym
subarachnoid bleeding; ruptured cerebral vessel

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: De Nederlandse Hartstichting

Intervention

Keyword: Coagulation/ fibrinloysis, Insulin resistance, Subarachnoid haemorrhage

Outcome measures

Primary outcome

Homeostatic assessment (HOMA)

Secondary outcome

parameters of:

-stress

-fibrinolysis

-coagulation

-endothelial function

-inflammation.

Study description

Background summary

After aneurysmal subarachnoid hemorrhage (SAH), hyperglycaemia is frequently observed and persists throughout in-hospital stay, also in the absence of diabetes mellitus (DM).
Recently, we found that after SAH, levels of fasting glucose are also frequent and independently predict the occurrence of delayed cerebral ischemia (DCI) and poor clinical outcome.
High levels of fasting glucose could represent a state of insulin resitance, such as discribed for patients with critical illness, patients admitted for trauma and after surgery. Insulin resistance has been linked to alterations in endothelial function, a pro-inflammatory state, coagulation and fibrinolysis that could predispose to secondary cardiovascular complications.

Several mechansims could explain a state of insulin resitance after SAH. First patients could already be resistant to insulin prior to the SAH such as is

often seen after ischemic stroke. Second, a transient stress reaction induced by the SAH with the activation of the sympathetic nervous system could induce insulin resistance. Third, the stress reaction could induce an altered glucose metabolism that persists throughout hospital stay or longer. Finally, tissue damage due to the SAH could lead to a profound inflammatory reaction, reflected by the release of pro-inflammatory cytokines such as tumor necrosis factor * (TNF-*) which in turn has been associated with insulin resistance. In conclusion, insulin resistance after SAH seems frequent and predicts DCI and poor clinical outcome. This however has never been characterized and if indeed such a state exists, it remains unclear whether this is was pre-existent to the SAH, only on admission, throughout hopsital stay or persistent on the long run. Furthermore it is unclear how this relates to systems involved in fibrynolysis, coagulation, inflamation and endothelial function in this patient group.

Study objective

The primary objective of the present study is to characterize the glucose metabolism in patients with SAH in the acute- and, sub acute phase and during follow-up.

The secondary objectives are to relate glucose metabolism to clinical condition on admission and during follow up and to parameters of fibrinolysis, coagulation, inflammation and endothelial function

Study design

Prospective cohort study

Study burden and risks

Patients will be asked to remain sober the first morning after inclusion, days 2-7 days after SAH, and days 10, 14 days and 17 after SAH. Finally also at follow up assessment. During admittence and at follow up, blood sugar and insulin levels have to be assessed 6 times extra, and patients will be asked to drink sugar water for the oral glucose tolerance test.
Also, during admittence and at follow-up we will measure weight, length and the hip and waist circumference.
Mentioned investigations do not carry significant risks.

Contacts

Public
Academisch Medisch Centrum

AMC H2-218
1100 DE Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

AMC H2-218
1100 DE Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with aneurysmal SAH in the last 48 hours

Exclusion criteria

(1) Under 18 years of age.
(2) A time lapse of more than 48 hours after SAH onset.
(3) Patients with diabetes mellitus.
(4) Renal insufficiency.
(5) Liver failure or a history of liver cirrhosis
(6) Admittance on or expected transfer to the intensive care unit.
(7) If death appears imminent.
(8) Pregnancy or lactation.
(9) Patients requiring oral tube feeding.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2008
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

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	NL21211.018.08