Skin Autofluorescence and Capillary Permeability: Relevance of Measuring Advanced Glycation Endproducts in Critically Ill Patients

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Objective of this study is to provide evidence for the induction of AGEs in blood and tissue in patients with septic shock.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Immune disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON31778

Source
ToetsingOnline

Brief title
AGEs in sepsis

Condition

- Immune disorders NEC
- Ancillary infectious topics
- Respiratory tract infections

Synonym
blood born infection, lung infection

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: advanced glycation endproducts, oxidative stress, sepsis, validation study

Outcome measures

Primary outcome

1. Survival rate in patients with severe septic shock and relationship with AGEs

2. Relationship of AGEs as measured in tissue, blood and as measured using the autofluorescence reader.

3. Relationship between sublingual microcirculation (and reversibility) and multi organ failure in septic patients.

Secondary outcome

1. Relationship between AGEs and capillary permeability in patients with sepsis

2. Relationship between AGEs and oxidative stress.

Study description

Background summary

Sepsis is characterized by the a severe inflammatory response. This inflammatory response is responsible for the develepment of organ dysfunction. Treatment aimed at this inflammatory response may reduce the mortality associated with the multiple organ failure. AGEs are a diverse class of compounds induced by an inflammatory response. The induction of AGEs was

previously thought to occur slowly over weeks to months, but recent data indicate that AGEs can also occur during acute inflammatory conditions. Investigating this response in patients with sepsis may provide the possibility to influence the inflammatory response via this pathway.

Study objective

Objective of this study is to provide evidence for the induction of AGEs in blood and tissue in patients with septic shock.

Study design

Prospective observational study with matched control group in which sublingual orthogonal polarization spectral imaging (OPS) is used to measure the microcirculation.

Study burden and risks

Obtaining skin biopsies is performed under local anesthesia. In addition, patients with severe sepsis are sedated and giving intravenous anesthetics as standard treatment. The extent of the burden of this skin biopsy (4 mm) is experienced as minimal-moderate by patients who have undergone this procedure in previous studies (MEC 98/10/172, METc 2001-233c, METc 2001-193, METc 2004.239). The other samples can be obtained with no extra burden or risks (blood sampling using an already placed intra-arterial line and autofluorescence is measured non-invasively). The injection of NaF can induce a temporarily discoloration of the skin, but this effect dissappears within 10 minutes.
The OPS measurement obtain no extra burden or risks for the patients.

Contacts

Public
Universiteit Maastricht

Postbus 616
6200 MD, mAASTRICHT
Nederland
Scientific
Universiteit Maastricht

Postbus 616
6200 MD, mAASTRICHT
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Written informed consent from close relative
2. Age > 18 years
3. Patient meets the general criteria for severe sepsis or septic shock, diagnosed less than 24 h prior to study inclusion.
4. and patients meets the general criteria for pneumonia.
5. Systemic arterial catheter in place with continuous pressure monitoring.
6. Patients in whom the clinician is prepared to provide full life support during the duration of the study.

Exclusion criteria

1. Shock due to any cause other than sepsis (e.g. drug reaction or drug overdose, pulmonary embolus, burn injury etc.)
2. Liver cirrhosis
3. (Insulin-dependent) diabetes mellitus
4. Patients on dialysis (CVVH or other)
5. Pre-existent urea cycle disorders or renal failure

Study design

Design

Study type:	Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-12-2006
Enrollment:	98
Type:	Actual

Ethics review

Approved WMO

Date:	23-10-2006
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	18-07-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL14501.068.06