Thorax injury in relation with systemic neutrophil activation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON31401

Source
ToetsingOnline

Brief title
THOR study

Condition

- Other condition

Synonym
Acute respiratory distress syndrome, ARDS, Pulmonary failure

Health condition

Trauma, immuunsysteem en longaandoeningen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Neutrophils, Pulmonary failure, Receptor expression profiles, Thorax trauma

Outcome measures

Primary outcome

Primary parameter: Activation of neutrophils (receptor profiles) and local

injury

Primary endpoint: Development of ARDS

Secondary outcome

Secondary endpoints:

Trauma severity (HTTSS / NISS / Blood gas on admission)

Difference between penetrating and blunt trauma

Study description

Background summary

Trauma is the major cause of morbidity and mortality in people under the age of 50. Morbidity and mortality are the direct result of the sustained injuries or indirectly due to post-injury complications like organ failure. Currently the treatment of organ failure is symptomatic. Prevention of organ failure is essential for a reduction in morbidity and mortality. Unfortunately, to date there is no tool for this, partically because the pathofysiologal processes that lead to organ failure are not completely understood. More insight in these processes is needed.

For the development of organ failure two factors are required: local endothelial activation or damage AND systemic inflammation. Severe thorax

trauma is frequently followed by pulmonary failure (ARDS). In thorax trauma there is always a certain amount of local tissue damage and systemic inflammation present. The development of ARDS is therefore dependent on the combination of systemic inflammation and local injury. This organ failure (ARDS) is mainly mediated by neutrophils. We developed profiles of receptor expression on neutrophils that reflect the systemic inflammatory status of the patient. The local (micro) injury can be identified by lung specific proteins in the circulation.

Study objective

The projects*goal is to gain insight in the pathofysiological processes after trauma that lead to organ failure. The hypothesis is that for the clinical presentation both severe systemic inflammation and severe local injury is needed. In the patient population of this study both factors are always present in different amounts. This results in the following questions:

Primary question:

Is there synergy between inflammation and tissue damage in the development of ARDS?

Secundary question:

Is there a relation between clinical scores for injury severity and the amount of inflammation and/or local tissue injury?

Is the cause of trauma (penetrating or blunt) of influence on the inflammatory response?

Study design

Patient, admitted to the hospital with an isolated thorax trauma (blunt or penetrating), are included. Patient informed consent or proxy consent is obtained as soon as possible. The severity of trauma is scored by various scoring systems (ISS, NISS, HTTSS). During admission the development of pulmonary complications and extra-pulmonary organ failure is recorded. These clinical start (traumascores) and endpoints (complications) are analyzed in the context of neutrophil expression profiles indicating the systemic inflammatory status of the patient and local injury by lung specific proteins.

On admission 5 ml Natrium-Heparin blood is set aside when regular laboratory assessment is done. Three and six hours after the trauma was sustained additional blood samples (5 ml Natrium-Heparin) is obtained. Twenty-four hours after the sustained injury 5 ml Natrium-Heparin is set aside when regular laboraty assessment is done. The samples are analyzed directly for their

receptor expression profiles by flowcytometry.

Study burden and risks

No risks, burden of 2 additional vena punctures.

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

Thorax trauma (AIS > 2)
Age 18 - 70

Exclusion criteria

Additional trauma (AIS > 2)
Immunological compromized (corticosteroids, chemotherapy)

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):	29-02-2008
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	04-12-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL16985.041.07