Mannose-binding Lectin Deficiency and the Risk of Infectious Complications in Trauma Patients.

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* Establish the relationship between plasma levels and the development of infectious complications. * Determine the genetic variants of the MBL-gene.

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON31242

Source
ToetsingOnline

Brief title
MBL Deficiency in Trauma

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
(Multiple) organ failure, Infections

Research involving
Human

Sponsors and support

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

Intervention

Keyword: deficiency, infectious complications, mannose-binding lectin, trauma

Outcome measures

Primary outcome

Plasma concentration levels of MBL in trauma patients.

Secondary outcome

Development of infectious complications and death within the first 30 days

after trauma in relationship to baseline and follow-up plasma levels of MBL.

- ISS, age, gender, region of injury, mortality.

- pneumonia, ARDS, SIRS, MOF, sepsis, wound infection, wound dehiscence,

urinary tract infection, intra-abdominal abscess.

Study description

Background summary

The role of genetics in developing infectious complications is made clear by recent studies. Genetic markers suspected are interleukins, tumor necrosis factor, HSP (heat shock protein), and PAI-1 (plasminogen-activator-inhibitor 1). Most of these markers are already investigated in relation to complication development in non-trauma patients.
A relatively risk factor for infectious complications is MBL (mannose-binding lectin) deficiency. The role of MBL deficiency in developing the most common infectious complications in trauma patients is still unclear.
Early detection of risk factors in trauma patients for developing one or more complications is of great importance to give insight in the pathogenesis of these disorders, leading to improved strategies for their prevention, diagnosis, and treatment. Therefore, in this study the role of MBL in complication development in trauma patients will be investigated.

Study objective

* Establish the relationship between plasma levels and the development of infectious complications.

* Determine the genetic variants of the MBL-gene.

Study design

Prospective cohort study.

Study burden and risks

First blood samples are taken concomitant with blood sampling for laboratory test as normal acute trauma care (shock room) procedure. Sampling at day 1 will be done simultaneously with standard laboratory tests as part of standard posttrauma care. Therefore risks will be low and comparable to blood samples taken under normal circumstances.

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

Trauma patients admitted to the shock room of the emergency department of the Academic Medical Center, Amsterdam. These patients either meet the criteria of high energy trauma, or are otherwise suspected to have potentially life threatening injuries.

Exclusion criteria

Patients younger then 18 years old.

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):	01-06-2007
Enrollment:	100
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	NL17553.018.07