Automated immune phenotyping and priming of neutrophils in a trauma cohort

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To investigate the feasibility of the implementation of a point-of-care immunological test based on blood cells of all trauma patients with the aid of an automated load-and-go flow cytometer in an acute trauma care setting at the shock room.

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

Summary

ID

NL-OMON46591

Source
ToetsingOnline

Brief title
Automated immune phenotyping in trauma

Condition

- Other condition

Synonym
accident, Trauma

Health condition

trauma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Neutrophil, Phenotyping, Trauma

Outcome measures

Primary outcome

Primary endpoint is reached if the following criteria are met:

- The Trauma surgeon (or assistant) is able to perform all the necessary

actions to start the blood analysis.

- Blood analysis was started <30 min after patient arrival in the trauma room.

- Interpretable data of neutrophil flow cytometry is saved on the attached

computer.

Secondary outcome

The secondary endpoint is defined as a difference in neutrophil phenotype

and/or response between the patients that develop infectious complications and

non-infectious trauma patients.

Study description

Background summary

The functional phenotype (decreased responsiveness) of circulating neutrophils (white blood cells) proved an adequate measurement of the amplitude of the immunological response after trauma. The (in)ability of neutrophils to respond

to bacterial stimuli (fMLF) directly after trauma (day 0) was related to the development of infectious complications, such as septic shock (>day 5). Infectious complications are heterogeneous in their presentation and require both local, host and environmental factors. The incidence of the most severe infectious complications decreased the past decade. Therefore, analysis of infections after injury has become even more complex and a large sample size is required to also include patients that will develop the most severe infectious complications. Until now, such a large study was not possible, as the analysis of differences in the functional phenotype of neutrophils was normally carried out by classical flowcytometry. This is time consuming, labor intensive and sensitive for human error. This is the reason why our previous discovery has not been implemented the daily clinical setting yet. However, analysis of neutrophil functionality can now 24/7 be performed automatically by a fully automated point-of-care flowcytometer (AQUIOS). Our study group adjusted and tested this machine in a controlled laboratory environment with a dedicated researcher measuring blood samples of healthy controls. This current implementation study investigates whether the AQUIOS can be implemented in a hectic clinical setting associated with the care of trauma patients. This will serve as a step-up to a large multicenter, international prognostic study for detecting and predicting infectious complications in trauma patients.

Study objective

To investigate the feasibility of the implementation of a point-of-care immunological test based on blood cells of all trauma patients with the aid of an automated load-and-go flow cytometer in an acute trauma care setting at the shock room.

Study design

A prospective study

Study burden and risks

A total of 4 milliliter blood will be collected from the patient once upon presentation in the trauma resuscitation bay in the emergency department. This will be combined with regular diagnostic blood sampling in order that no extra puncture is necessary. Sampling of this amount of blood will not diminish the total volume of circulating blood in the vasculature of these patients and the additional risk for clinical signs and symptoms due to anemia is non-present. The patients participating in this study will not benefit of this measurement.

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

All trauma patients presented at the trauma bay in the emergency department of the UMCU, that need to undergo blood sampeling. Age must be at least 18.

Exclusion criteria

Patient transferred from other hospitals to the UMC Utrecht.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	26-11-2018
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	AQUIOS flowcytometer
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	31-10-2018
Application type:	First submission
Review commission:	METC NedMec

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	NL64100.041.17

Study results

Date completed: 01-02-2020

Results posted: 26-05-2020

First publication
25-05-2020