Automated immuno phenotyping of neutrophils in geriatric hip fracture patients, the AQUIOS study

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1. Implementation of a point-of-care fully automated analysis of neutrophils in the emergency department trauma bay in monotrauma geriatric hip fracture patients. 2. To determine if patients who develop infectious complications demonstrate decreased...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint injuries
Study type	Observational invasive

Summary

ID

NL-OMON49050

Source
ToetsingOnline

Brief title
AQUIOS study

Condition

- Bone and joint injuries

Synonym
broken hip, hip fracture

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: St. antonius ziekenhuis;evt. onderzoeksfonds

Intervention

Keyword: geriatric, immunology, neutrophils, trauma

Outcome measures

Primary outcome

The main study endpoint is reached if the AQUIOS is started <30 minutes after blood withdraw and the flowcytometry data is saved in the computer. The study is defined as successful if het test is rightly done in >80% of all included patients.

Secondary outcome

The secondary endpoints are defined as

- a difference in protein expression and/or neutrophil responsiveness between the patients that develop infectious complications and patients who do not.

- a difference in pH, PvO2, PvCO2, or HCO3- between the patients that develop infectious complications and patients who do not.

Study description

Background summary

The functional phenotype (decreased responsiveness to fMLF) 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 late 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 responsiveness of neutrophils was normally carried out by classic flowcytometry. This is time consuming, labor intensive and sensitive for human error. This is the reason why our previous discovery has not been implemented in a daily clinical care yet. However, analysis of neutrophils can now 24/7 be performed automatically by a fully automated point-of-care flowcytometer (AQUIOS).

Study objective

1. Implementation of a point-of-care fully automated analysis of neutrophils in the emergency department trauma bay in monotrauma geriatric hip fracture patients.

2. To determine if patients who develop infectious complications demonstrate decreased neutrophil responsiveness and protein expression comparable to trauma patients without infectious complications

3. To determine if patients who develop infectious complications demonstrate differences in pH, PvO2, PvCO2, or HCO3- comparable to trauma patients without infectious complications

Study design

A prospective cohort study, diagnostic research

Study burden and risks

A total of 8 milliliter blood will be collected from the patient once upon presentation in the trauma resuscitation bay in the emergency department, usually within the first 5 minutes after presentation. 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

70 years old or above
Subtrochanteric, pertrochanteric, or femoral neck fracture

Exclusion criteria

< 70 years
pathological fracture (i.e. suspect for malignancy)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2021
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	16-02-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL74282.100.20