Proteomics after ankle-joint-fractures

Published: 11-08-2006 Last updated: 20-05-2024

The following questions will be answered:• Can typical protein-profiles in a proteomic-assay be identified after trauma, which might be correlated with the outcome of the patients?• How is the dynamic of protein-profile-changes in the proteomics-...

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

Summary

ID

NL-OMON29803

Source ToetsingOnline

Brief title Proteomics after ankle-joint-fractures

Condition

• Bone and joint injuries

Synonym ankle-fractures

Research involving Human

Sponsors and support

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

Intervention

Keyword: ankle, early inflammation, fractures, proteomics

Outcome measures

Primary outcome

Proteomic-profile after isolated ankle-fracture on day 0 (day of trauma) and

day 1, 3, 5, 7, 14, 21, 28, 3 months after trauma.

Secondary outcome

none

Study description

Background summary

After severe trauma serious haemorrhage, severe head trauma and multiple organ failure are still the most important causes of death. Especially in patients with a combination of severe haemorrhage or head trauma and extremity-lesions the question of optimal timing of the operation as well as the choice of type of fracture stabilization is still un-answered. The key-point in this issue is the amount of trauma-load of a patient and the possibility to tolerate a *second-hit* like operations. The search for prognostic and determinant factors for estimating outcome of a trauma-victim in the last years was very intensive. The complexity of the systemic acute phase reaction to trauma might be the reason why *the golden bullet* couldn*t be found yet. Proteomics might be a tool to answer these unsolved questions.

Study objective

The following questions will be answered:

• Can typical protein-profiles in a proteomic-assay be identified after trauma, which might be correlated with the outcome of the patients?

• How is the dynamic of protein-profile-changes in the proteomics-essay in the healing-process?

Study design

We will include all adult patients with an isolated ankle-fracture. Exclusion-criteria*s beside age are relevant co-morbidities and defeating of the study. So we want to include patients with an ASA-classification of 1 or 2. We want to include 20 patients.

For getting a good dynamic of the protein-profiles a continuous collecting of

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blood-samples is extremely important.

The following time points for blood-sampling are planned:

Day 0 (day of trauma)

Day 1, 3, 5, 7, 14, 21, 28, 3 months.

All samples will be taken round about 11 o*clock.

The blood-samples are taken immediately to the CHIC (surgical intensive care) were centrifuge is available. By a temperature of 4°C and with 2500 rpm the test tubes will be centrifuged for 10 minutes. Afterwards the serum will be divided in several eppendorff-tubes and placed in the freezer by -70°C. All tubes will be marked following the prepared code-numbers. The first character of the code represents the patient-number and the second the number of the probe.

The proteomics are measured by the Groninger proteomics-lab. The results will be correlated with the outcome and healing process of the patients. Therefore the information*s of the patient-dossier are needed.

Study burden and risks

Very low risk for the patients. There is only a punctering of the cubital vein necessary.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Older than 17 years, isolated fracture of an ankle, accordance with the study, ASA 1 and 2

Exclusion criteria

Pat. refuses to join, ASA > 2, multiple injury

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2006
Enrollment:	20
Туре:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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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 CCMO ID NL13000.042.06