Side Stream Dark Field Imaging of the Sublingual Microcirculation In Trauma Patients

Published: 28-06-2007
Last updated: 14-05-2024

·Establish the sublingual Microvascular Flow Index (MFI) in trauma patients and the relationship between shock class, as defined by the American College of Surgeons and MFI.·Demonstrate correlation between shock-room MFI measurements and mortality…

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

Summary

ID

NL-OMON30639

Source
ToetsingOnline

Brief title
SDF in Trauma

Condition

- Other condition

Synonym
shock

Health condition

circulatoire shock bij trauma patienten

Research involving
Human

Sponsors and support

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

Intervention

Keyword: microcirculation, resuscitation, shock, Trauma

Outcome measures

Primary outcome

MFI in trauma patients stratified by shock class, as defined by the American

College of Surgeons.

Secondary outcome

Predictive value of the MFI at T1 and T2 for mortality and MOF in comparison to

Base Excess, Lactate and Shock Class.

Heart rate; systolic, mean and diastolic blood pressure; temperature;

respiratory rate.

Arterial blood gases; lactate; total blood count; electrolytes; pre-hospital

administration of vaso-active drugs, use of IV fluids (transient/non

responders). SOFA score, ISS

Study description

Background summary

Tissue dysoxia in critically ill patients is regarded as the major factor leading to multisystem organ Failure (MOF) and higher mortality rate. Early correction of tissue dysoxia may prevent progression to organ failure and provide maximal benefit in terms of outcome. Therefore, early detection and correction of tissue dysoxia is of great importance.

The traditional systemic hemodynamic and oxygenization variables are relatively nonspecific and have limited roles in detecting persistent global tissue dysoxia and may be normal in early stages of circulatory shock. Visualization of microcirculation is a promising method for early detection of tissue dysoxia. The microcirculatory disturbance occurs earlier than usual indicators in shock. Additionally, microcirculatory alterations correlate to the severity of shock and these alterations predict patient outcome better than traditional markers.

Study objective

·Establish the sublingual Microvascular Flow Index (MFI) in trauma patients and the relationship between shock class, as defined by the American College of Surgeons and MFI.
·Demonstrate correlation between shock-room MFI measurements and mortality and occurrence of MOF.
·Compare the predictive value of the MFI for mortality and MOF to conventional resuscitation endpoints.

Study design

Prospective, non randomised, descriptive observational study.

Study burden and risks

Measurements can only be done after informed consent is obtained from the patient or a legal representative. Verbal informed consent will be documented by a witness. As soon as a patient is capable, written informed consent is obtained.The risks of the 2 SDF measurements, comparable to oral temperature measurement, are negligible. Therefore we consider use in patients with impaired consciousness acceptable, especially since our study population is very likely to suffer from impaired consciousness. The measurements will be performed by a separate investigator, in order not to interfere with normal ATLS-trauma care procedures. T1 laboratory results can be taken from the standard blood samples taken from trauma patients. The T2 blood samples are usually taken, but might in selected cases warrant an extra (arterial) blood gas puncture. With each arterial blood gas sample taken, there*s a risk of getting a haematoma. Systemic hemodynamic and oxygenization variables will be measured as part of the normal evaluation of trauma patients. Outcome data will be derived from patient files.
There is no direct benefit for the participant.

Contacts

Public
Academisch Medisch Centrum

Postbus 22660
1100DD Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Postbus 22660
1100DD Amsterdam
Nederland

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

Younger than 18. No informed consent

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:	75
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	NL12142.018.06