The microcirculation in the pathogenesis of organ failure in patients with acute heart failure.

Published: 12-11-2007
Last updated: 09-05-2024

We want to prove in at least 100 patients admitted with acute heart failure that:1. Microcirculatory blood flow alterations exist in the early course of disease (i.e. preferably measured before the start of treatment).2. SDF imaging is a useful...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON30972

Source
ToetsingOnline

Brief title
CARMICI - protocol B

Condition

- Heart failures

Synonym
Cardiogenic shock, severe heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiogenic shock, Microcirculation, Multiple organ failure, Sidestream Dark Field imaging

Outcome measures

Primary outcome

1. Microvascular flow index, as obtained by SDF imaging.

2. Daily SOFA scores, as a measure for (multiple) organ failure.

3. Survival.

Secondary outcome

Data collection:

1. Clinical: Gender, age, length, weight, body temperature, Glascow Coma Scale,

APACHE IV score, SAPS II score, diuresis.

2. (Macro)Hemodynamics: Heart rate, arterial blood pressure, central venous

pressure, cardiac output, pulmonary artery pressure, pulmonary wedge pressure.

3. Respiratory: Positive end expiratory pressure (PEEP), respiratory rate.

4. Laboratory: Arterial blood gas analysis (pH, PaCO2, PaO2, SaO2), central

venous blood gas analysis (ScvO2, PvCO2), lactate, glucose, hemoglobin (Hb),

hematocrit (Ht), urea, creatinin, thrombocytes, leukocyrtes, PT/APTT/ACT.

5. Oxygen delivery: DO2=CO*13.4*[Hb]*SaO2.

6. Oxygen uptake: VO2=CO*13.4*Hb*(SaO2-SvO2).

Study description

Background summary

Microcirculation is the part of the circulation where nutrients, water, gases, hormones, and waste products are exchanged between the blood and cells. The microcirculation consists of a network of blood vessels less than 100 µm in diameter (arterioles, capillaries and venules, respectively). An adequate blood flow within these microvessels is a prerequisite for normal organ perfusion. The microcirculation also functions as a volume reservoir for blood, so that the microcirculation plays an important role in regulating preload and cardiac output of the heart. Another major function of the microcirculation is to regulate vascular resistance to maintain an adequate arterial pressure. Regulation of vascular resistance to preserve the arterial pressure (by constriction of the resistance vessels) and allowing each tissue to receive sufficient blood flow to sustain metabolism are sometimes in conflict. Often the temporary compromise is to preserve the mean arterial pressure by increasing arterial resistance at the expense of reduced blood flow to most organs; ultimately, however, the tissue exchange function must be restored. In patients with circulatory failure ("shock"), blood flow is diverted from the less important tissues (skin, subcutaneous, muscle, gastrointestinal tract) to vital organs (heart, brain, kidneys). Multiple organ failure is common in these patients, often despite correction of the alterations in, for example, heart rate, arterial blood pressure and cardiac output. It is believed that redistribution of blood flow away from the splanchnic area may result in translocation of microorganisms from the gut into the blood and that may be one of the factors contributing to the development of multiple organ failure. Micro-circulatory blood flow alterations may play an important role in this process.
Acute heart failure is classified into several clinical conditions. One of the most threatening is cardiogenic shock. The European Society of Cardiology (ESC) defines cardiogenic shock as evidence of tissue hypoperfusion induced by heart failure after correction of preload. There is no clear definition for hemodynamic parameters, but cardiogenic shock is usually characterized by reduced blood pressure (mean arterial pressure <65 mmHg), a pulse rate >60 beats per min., cardiac output <2.2 l/min/m2 and low urine output (<0.5 ml/kg/hr). The most common cause of cardiogenic shock is a large acute myocardial infarction. Mortality of patients with cardiogenic shock remains high despite agressive revascularization procedures and modern hemodynamic and respiratory support. Many of these patients experience either fatal arrhythmias or die with a low cardiac index ("pump failure"). Furthermore, a substantial number of patients with cardiogenic shock die with a normalized cardiac index ("normalized" with inotropes and/or an intra-aortic balloon pump). We hypothesize that within these latter patients local microcirculatory blood flow alterations play an important role in a process that finally leads to death.

Study objective

We want to prove in at least 100 patients admitted with acute heart failure that:
1. Microcirculatory blood flow alterations exist in the early course of disease

(i.e. preferably measured before the start of treatment).
2. SDF imaging is a useful bedside tool to evaluate the time course of microvascular alterations.
3. There is a correlation between microcirculatory alterations and the degree of organ failure.
4. Microcirculatory perfusion can be changed by common treatment strategies.

The final objective of the study is to investigate whether that the microcirculation might be a new therapeutic target in patients with severe heart failure and cardiogenic shock. The knowledge obtained from this pilot project will result in the start of future trials, which should investigate whether improvement of microcirculatory flow will have an effect on outcome.

Study design

An observational study will be performed at the Intensive Care Unit of the Thoraxcenter of the Erasmus University Medical Center Rotterdam.

Study burden and risks

The study will be observational. SDF imaging is a noninvasive method and recording of SDF sequences can be obtained within a few minutes. Collection of the other parameters will be based on routine measurements as much as possible.

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

1. Age of 18 years or older.
2. Admitted with the diagnosis acute heart failure (criteria: see protocol).

Exclusion criteria

1. Pregnancy (results in an altered hemodynamic state).
2. Oral bleeding.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-11-2007
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	12-11-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL18966.078.07