Microcirculatory perfusion alterations in severe burn injury

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Primary Objective: To assess the incidence of microcirculatory perfusion alterations, according to a predefined arbitrary cut off value, in patients with severe burns injury (>15%TBSA) during standard resuscitation in the first 24 hours.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Epidermal and dermal conditions
Study type	Observational invasive

Summary

ID

NL-OMON47089

Source
ToetsingOnline

Brief title
MIPA trial

Condition

- Epidermal and dermal conditions
- Decreased and nonspecific blood pressure disorders and shock

Synonym
burns, fluid resuscitation

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: subsidie aanvraag van ned brandwonden stichting

Intervention

Keyword: burns, ic patients, microcirculation, resuscitation

Outcome measures

Primary outcome

Main study parameters/endpoints: Standard operating procedure for measurement of microcirculatory perfusion (sublingual tissues): vessel density parameters, microvascular flow index and flow heterogeneity will be measured on admission (T=0) and after 4, 8, 12 and 24 hours.

Secondary outcome

Skin perfusion maps (Laser Speckle Imaging) will be recorded. Skin perfusion maps will be displayed in unaffected skin and wounds of different burn depth. (2nd and 3rd degree burn depth) on predetermined different times.

Blood and urine samples: Blood and urine samples will be collected at the certain time points to be analysed for syndecan, hyaluronic acid, heparin sulfate, MDA, free-Hb and Ni/Na

Study description

Background summary

There are valid concerns that resuscitation in burns shock is inadequate. A tendency to over resuscitate patients seem to exist. Current guidelines were developed 35 years ago and clinical burn resuscitation had not advanced significantly, despite ongoing research. The main goal of resuscitation is achieving organ perfusion and tissue oxygenation. Inadequate fluid resuscitation of severe acute burns may result in hypovolemic shock and death. Excessive fluid resuscitation may result in fluid overload, lung edema, intra-abdominal hypertension, abdominal compartment syndrome and burn depth conversion with increased requirement for escharotomies, fasciotomies and skin grafting.

Hypo perfusion caused by insufficient resuscitation may result in glycocalyx shedding, aggravation of the inflammation and oxidative stress too which may finally deteriorate outcome of a burn patient.
To date, the Parkland formula is the most used formula worldwide for resuscitation of the acute burn patient. In this formula, 4cc/kg/% lactated Ringers solution per percentage total body surface area (TBSA) is administered in 24 hours of which the half in the first 8 hours. However, this formula has some well-known restrictions; this formula necessitates large amount of fluids, which need a close monitoring of clinical and laboratory parameters for the control of the massive fluid infusion
Monitoring of adequacy of resuscitation in burns patients have always been guided by systemic hemodynamic variables (macro circulation) like blood pressure, heart rate, stroke volume and urinary output, being urine output the major indicator of successful resuscitation. Whether these end points are successful in achieving adequate perfusion and oxygen transport to the tissues is unknown and relies on the assumption that there is a hemodynamic coherence between the macro and microcirculation whereby improving the macro circulation causes a parallel improvement in the microcirculation. However, emerging evidence shows that targeting systemic hemodynamic variables gives inadequate guarantee for correction of tissue perfusion by fluid therapy. Very recently, Hernekamp et al described that stabilisation of the macrodynamic conditions did not neccessarilay have a positive effect on the macro circulation in severe burned rats (TBSA 30%).
Tissue monitoring devices have been described by Venkatesh et al. They found that despite acceptable clinical indices of global perfusion during resuscitation of severely burned patients, the splanchnic circulation in both burned and normal skin remained compromised. In the past it was very difficult to monitor the microcirculation at bedside. However, due to recent technological advances it is possible to easily assess microcirculatory perfusion of critically ill patients. Observation of the microcirculation adds important measurements to conventional systemic monitoring of the macrocirculation. Blood flow in the microcirculation can be assessed at the bedside by means of a handheld sublingual microscope (Cytocam IDF) and Laser Speckle Imaging. Cytocam IDF is a technologically new advanced version of hand held microscopes (Cyto Cam, Braedius Medical, Huizen, The Netherlands) and able to perform sublingual microcirculatory images. Laser Speckle imaging (LSI) is a non-invasive non-contact method which can be used to evaluate blood flow in the microcirculation in burns of different depths. Applying these non-invasive bedside techniques in the clinical setting of severe burns patients will allow us to see how the current resuscitation regime based on targeting systemic macro circulatory targets effects the microcirculation and tissue perfusion.

Study objective

Primary Objective: To assess the incidence of microcirculatory perfusion alterations, according to a predefined arbitrary cut off value, in patients with severe burns injury (>15%TBSA) during standard resuscitation in the first

24 hours.

Study design

Study design: The design is a monocenter, prospective, observational clinical study in the Maasstad Hospital.

Study burden and risks

negligable risk of participation in this study.
Sublingual cytocam measurement is non invasive and the probe is covered with a sterile disposable cap for each patient
laser speckle image in non contact non invasive
blood samples are withdrawn via a standard inserted arterial canula (so no extra burden) . Only risk is theoretical risk of anemia for sampling blood.

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

burns TBSA>15%
(total body surface area)

Exclusion criteria

no informed consent
suspected serious infection

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-11-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	15-09-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	29-08-2018
Application type:	Amendment
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	NL60162.101.16