Distribution and time course of serum procalcitonin levels in burn patients.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON39277

Source
ToetsingOnline

Brief title
Serum procalcitonin measurements in burn patients.

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Injuries by physical agents

Synonym
Burns, thermal injury.

Research involving
Human

Sponsors and support

Primary sponsor: Rode Kruis Ziekenhuis
Source(s) of monetary or material Support: BRAHMS

Intervention

Keyword: Burn patients., Procalcitonin., Sandwich immuno-assay., Serum.

Outcome measures

Primary outcome

Values and course of serum PCT measurements.

Secondary outcome

None.

Study description

Background summary

Patients with burns exceeding 15% body surface area usually meet the criteria of the Systemic Inflammatory Response Syndrome (SIRS). Sepsis is a clinical entity which is defined by SIRS criteria plus the presence of an infection. Clinically, SIRS is indistinguishable from sepsis. Therefore, other criteria are needed to prove the presence of an infectious agent. Proof of infection is attained when positive cultures of blood, sputum or other patient material are found together with a high likelihood of pathogenicity of the agent i.e. the laboratory results match the clinical picture. It is estimated that in only 20-30% of cases the diagnosis sepsis is supported by matching, postive cultures. When antibiotic therapy is started before obtaining cultures this number drops to approximately 1%.
Serum procalcitonine as a tool to detect infection has already been investigated in several clinical settings with variable success. This is also the case for burn patients. Up till now, however, prospective data for serum procalcitonine values over a broad detection range in burn patients are lacking. This study, together with the availability of a new, very sensitive assay, aims to fill this gap. The data forthcoming from this study may help to make the difficult, but important distinction between SIRS caused by burns on one hand and SIRS complicated by a concomitant infection on the other hand.

Study objective

This study aims to design a nomogram for the course of serum pro-calcitonin in burn patients. For this purpose, a new, sensitive assay will be used. It is expected that the nomogram will help to differentiate between patients with a systemic inflammatory response syndrome (SIRS) that is the result of the burn

wound and patients with a SIRS and a concomitant bacterial infection. Distinction between these 2 patient populations will provide a rationale for the start of antibiotic therapy.

Study design

Open, prospective, observational study design.
Serum procalcitonin values will be measured from admittance until discharge of the patient from the burn intensive care unit with a maximum of 14 days (calculated from the day of the burn injury).
Serum PCT measurements will be performed together with routine laboratory measurements.

For each included patient, data will be collected to describe the population studied. In addition, data that are expected to correlate with the course and height of serum PCT measurements are collected.

The following data will be collected:

- Type of burn injury (flame, scald, chemical).
- Alcohol intake.
- Substance abuse (yes/no).
- Age, height, weight.
- Medication on admittance.
- Smoking (yes/no, if yes approximate amount of cigarettes per day).
- Concomitant injury (yes/no).
- If yes: head injury, thoracic injury, abdominal injury, injury to extremities, or otherwise.
- Calculated burned surface area.
- Co-morbidity, present before burn injury:
- Neurological.
- Cardiovascular (myocardial infarction, valve pathology, rhythm disturbacies, cardiac failure, peripheral vascular insufficiency, thrombosis).
- Pulmonary: asthma, chronic obstructive pulmonary insufficiency.
- Renal failure: estimated glomerular filtration rate before admittance.
- Endocinological (diabetes, thyroid, otherwise).
- Other co-morbidity.
- Deficient immune system (yes/no, if yes cause).

Time schedule for PCT measurements.

- At admittance.
- Every 12 hours during first 3 days (calculated from time of burn injury).
- Daily from day 4 until discharge from burn intensive care unit or until day 14 after burn injury.

The following laboratory data will be collected on a daily basis:

- Leucocyte count.
- C-reactive protein.
- Serum sodium, potassium, creatinine.
- Clinical variabels:
- Temperature (highest/lowest) (°C).
- Systolic blood pressure (highest/lowest) (mmHg).
- Diastolic blood pressure (highest/lowest) (mmHg).
- Heart frequency (highest/lowest) (min-1).
- Fluids administered, diuresis, fluid balance).
- Dialysis (yes/no).
- Patient on ventilator (yes/no).
- Type of ventilation.
- Mean pressure (highest/lowest) (mmHg).
- Peak pressure (highest/lowest) (mmHg).
- PEEP (highest/lowest)(mmHg).
- FiO2 (highest/lowest).
- Oxygen delivered (calculated depending on mode of delivery e.g. face mask, nasal cannula).
- Medication.
- Inotropic medication (yes/no).
- Dopamin (highest/lowest) (ml/h).
- Noradrenalin (highest/lowest) (ml/h).
- Enoximone (highest/lowest) (ml/h).
- SDD (yes/no).
- Glucocorticoids parenteral (yes/no).
- Antibiotics parenteral (yes/no).
- Antibiotics by nebulizer (yes/no).
- Antibiotics orally (yes/no).
- Type of wound covering.
- Events.
- Operation (yes/no).
- Insertion of intravenous catheter (yes/no, if yes: place of insertion).
- Positive culture (yes/no).
- Blood (date, type of infectious agent, contamination likely (yes/no).
- Sputum (date, type of infectious agent, contamination likely (yes/no).
- Wound (date, type of infectious agent, contamination likely (yes/no).
- Other focus.

Study burden and risks

Blood will be drawn from the patients at times of routine blood laboratory measurements. The burden for the patients will consist of the withdrawal of approximately 4 ml extra blood per 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

Burns exceeding 20% body surface.
18 years and older.

Exclusion criteria

No consent.
Known infection present on admittance.
Patient expected to die within 24 hours.

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):	01-06-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	17-02-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2013
Application type:	Amendment
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	NL31722.029.10