

Immunological factors of pain and infection in patients with burns

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First, to explore relationships between immunological factors (cytokines and chemokines), psychological stress, and pain, controlled for infection. Second, to explore relationships between immunological factors (MBL), bacterial colonisation and...

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

Summary

ID

NL-OMON39434

Source

ToetsingOnline

Brief title

Pain and infection in burns

Condition

- Other condition
- Bacterial infectious disorders
- Epidermal and dermal conditions

Synonym

Pain and infection in burns

Health condition

infectie en pijn bij brandwonden

Research involving

Human

Sponsors and support

Primary sponsor: Vereniging Samenwerkende Brandwondencentra Nederland

Source(s) of monetary or material Support: Nederlandse Brandwonden Stichting

Intervention

Keyword: Burns, Immunology, Infection, Pain

Outcome measures

Primary outcome

Main objectives are to analyse cytokines (IL-6, IL-10, TNFalpha), cortisol, chemokines and MBL in residual blood samples. Levels of cytokines and cortisol will be correlated with self-reported pain and psychological problems (peri-traumatic reaction to accident, depression, and anxiety) and controlled for infection. MBL levels and genotypes will be examined in relation to bacterial presence and wound healing. Levels of cytokines in eschar will be examined and correlated to pain scores.

Secondary outcome

We want to explore a possible relationship between cortisol on day 1 and the subjective peri-traumatic reaction to the burn event.

Study description

Background summary

Control of pain and infection constitute continuing challenges in patients with burns. Although behavioural studies describe many influencing factors, biological mechanisms of pain are still insufficiently understood. A recent study in rats, showed an interesting connection between pro-inflammatory cytokines and pain. The current study will investigate this correlation in patients with burns. In addition, we will explore a possible connection between psychological distress, pro-inflammatory cytokines, and pain. We hypothesize

that a higher level of pro-inflammatory cytokines is associated with higher psychological stress, and higher self-reported pain. An important confounder of immunological factors in the pain study, is infection; infected wounds are more painful and influence the immunological factors. For that reason, microbiological and/or infection status will be documented in detail and will be controlled for in the analysis.

The second part of this study focusses on infection. Prevention of microbial contamination and infection is vital for burn wound care. In burn wounds, *Staphylococcus aureus* and *Pseudomonas aeruginosa* are the most frequently isolated microbial species. Bacterial presence can result in wound healing problems but not in all patients. One factor that may predispose patients to *P. aeruginosa* is part of the inflammatory response after skin injury: the mannose-binding lectin (MBL). MBL is a broad-spectrum pattern recognition molecule that plays a key role in innate immunity. A growing consensus from studies in humans and mice suggests that a low serum level of MBL together with other comorbid factors predisposes the host to increased susceptibility to infection. We hypothesize that low levels of MBL increases the risk of bacterial colonisation.

Study objective

First, to explore relationships between immunological factors (cytokines and chemokines), psychological stress, and pain, controlled for infection. Second, to explore relationships between immunological factors (MBL), bacterial colonisation and wound healing.

Study design

Prospective observational cohort study with a duration of 1.5 year.

Study burden and risks

The burden of the study is limited to the completion of questionnaires during the study period. To our knowledge, the completion of questionnaires is not associated with any risk for the subjects.

The blood puncture procedures are embedded in the clinical routine. On one occasion - after having given informed consent - an extra blood tube will be taken during a clinical routine vena puncture. Importantly, there is no puncture for research purposes only.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

$\geq 5\%$ total burned surface area
Able to understand research information and able to give informed consent

Exclusion criteria

$< 5\%$ total burned surface area
Not able to understand Dutch

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: 55

Type: Actual

Ethics review

Approved WMO

Date: 25-07-2011

Application type: First submission

Review commission: METC Noord-Holland (Alkmaar)

Approved WMO

Date: 12-02-2013

Application type: Amendment

Review commission: METC Noord-Holland (Alkmaar)

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

NL35972.094.11