Immunological factors of pain and infection in patients with burns

Published: 25-07-2011 Last updated: 28-04-2024

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

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 unsufficiently 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 punction 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 punction. Importantly, there is no punction for research purposes only.

Contacts

Public

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Vereniging Samenwerkende Brandwondencentra Nederland

Zeestraat 29 Beverwijk 1941 AJ NL **Scientific** Vereniging Samenwerkende Brandwondencentra Nederland

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

>= 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
Туре:	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.

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In other registers

Register

ССМО

ID NL35972.094.11