Evaluation of the skin window technique in patients with complex regional pain syndrome

Published: 18-03-2008
Last updated: 11-05-2024

The current study aims to gain better insight into the pathophysiology of the aberrant inflammatory response in CRPS. The evaluation of the role of pro-inflammatory and anti-inflammatory mediators in response to a microtrauma may generate important...

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

Summary

ID

NL-OMON32121

Source
ToetsingOnline

Brief title
Skin window technique in CRPS

Condition

- Injuries NEC

Synonym
Complex Regional Pain Syndrome, Posttraumatic Dystrophy, Reflex Sympathic Dystrophy

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ministerie van Economische zaken

Intervention

Keyword: CRPS, inflammatory reaction, skin-test

Outcome measures

Primary outcome

Primary outcome are the differences between patients and controls with respect to cytokine profiles, de availability and amount of myeloperoxidase and the total amount of Gc-globulin and 1,25(OH)2vitaminD3.

Secondary outcome

Secondary outcome is the difference within patients when comparing between the affected and the unaffected arm. Another secondary outcome is the difference within control subjects when comparing between both arms.

Study description

Background summary

CRPS frequently follows trauma, which can be minimal or severe. Several features of CRPS in reaction to this trauma, such as pain, changes in skin blood flow and temperature, sweat secretion and swelling, suggest an inflammatory origin. Compelling evidence suggests involvement of C- and Aδ fibers of sensory nerves (neurogenic inflammation) and local immune system of the skin. However, key factors that mediate this aberrant inflammatory response have not yet been identified. Current research is aims to provide more insight into this matter.

Study objective

The current study aims to gain better insight into the pathophysiology of the aberrant inflammatory response in CRPS. The evaluation of the role of pro-inflammatory and anti-inflammatory mediators in response to a microtrauma may generate important information on the biological pathways involved in CRPS.

Study design

Patients (n=30) and controls (n=30) are each randomized into three groups. Skin windows are created at the volar surface of the forearm by dermal abrasion, which continues until capillaries are seen but ceases before bleeding starts. These skin windows are overlaid with filter paper containing either saline alone (group 1), or saline containing LTA (group 2) or lipid A (group 3). The last two groups are used to stimulate the inflammatory response.

Two skin windows per arm are needed. One filter paper per arm is removed after 30 minutes for measurements of baseline situation, and replaced by new filter papers. The other filter papers (one per arm) are removed two hours after skin window formation, for measurements of the acute phase response. The skin window used for the measurement of baseline situation will also be used (with new filter papers) for assessment of the late response after 24 hours.

Intervention

na

Study burden and risks

Patients and control subjects will come to the LUMC at two consecutive days. The first visit will take 2.5 hours, on the second day the visit is only 10 minutes.

Side effects caused by this study are expected to be minimal. Dermal abrasion can cause redness, swelling and an uncomfortable feeling at the area of the skin window. Application of LTA or lipid A can cause flare and swelling.

Contacts

Public
Leids Universitair Medisch Centrum

postbus 9600
2300 RC Leiden
Nederland
Scientific
Leids Universitair Medisch Centrum

postbus 9600
2300 RC Leiden
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Patients should fulfill the criteria for CRPS I according to the clinical diagnostic criteria of the IASP:
o Continuing pain, allodynia or hyperalgesia that is not limited to the territory of a single peripheral nerve and is disproportionate to the inciting event.
o Evidence at some time of edema, changes in skin blood flow or abnormal sudomotoric activity in the region of the pain
o This diagnosis is excluded by the existence of conditions that would otherwise account for the degree of pain and dysfunction. ;* Patients should fulfill the diagnostic criteria for CRPS I according to Veldman:
o Four or five of:
* Unexplained diffuse pain
* Difference in skin color relative to the other limb
* Diffuse edema
* Difference in skin temperature relative to the other limb
* Limited active range of motion
o Occurrence or increase of the above signs and symptoms after use
o The above signs and symptoms are present in an area larger than the area of primary injury or operation and include the area distal to the primary injury. ;* Patients should have one affected and one unaffected arm.

Exclusion criteria

* Patients and controls should have no history of any (other) chronic inflammatory diseases.
* Patients and controls are excluded when immunosuppressive medication is used.
* Patients and controls are excluded when having an infectious disease at the time of the measurements.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-07-2008
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL20217.058.07