Muscle biopsie for Acute Complex Regional Pain Syndrome Type I from one extremity for mitochondrial research

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Does mitochondrial dysfunction play an important role in the pathofysiology of patients with Complex Regional Pain Syndrome Type I ?

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neuromuscular disorders
Study type	Observational invasive

Summary

ID

NL-OMON35752

Source
ToetsingOnline

Brief title
Muscle biopsie for Acute CRPS I for mitochondrial research

Condition

- Neuromuscular disorders

Synonym
Complex Regional Pain Syndrome Type I, Reflex Sympathetic Dystrophy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Fondswerving van externen (Anna Fonds) is ingediend

Intervention

Keyword: CRPS I, Energy metabolism, Mitochondria, Pathofysiology, Skeletal muscle

Outcome measures

Primary outcome

Difference in mitochondrial function between muscle of CRPS I extremity and the

contra lateral extremity

Secondary outcome

Not Applicable

Study description

Background summary

Complex Regional Pain Syndrome (CRPS) is a potentially incapacitating syndrome, that may occur after a minor injury or an operation applied to a limb. CRPS has impact on all tissues and may impair all functions of that extremity, leading to severe disability and almost intractable
pain. The spectrum of symptoms and signs is wide. The early phase is characterized by signs and symptoms of inflammation including excessive pain and impaired motor and sensory function. The late phase is characterized by trophic changes of all tissues. In approximately 10 percent of the cases CRPS occurs without a preceding trauma. Formerly CRPS was denominated as causalgia, algodystrophy, Sudecks atrophy or reflex sympathetic dystrophy. In 1994 the International Association for the Study of Pain (IASP) coined the term Complex Regional Pain Syndrome type I (CRPS I). In CRPS type II (causalgia) nerve damage must be present.

In patients with acute CRPS I, our department found significantly elevated SvO2 levels, obtained from the vena cubiti or vena femoralis in the affected extremity, as compared to samples obtained from the unaffected contralateral limb and as compared with healty volunteers.
We conclude from these data that the high SvO2, which suggests defective oxygen metabolism, cannot fully be explained by an oxygen diffusion problem. We therefore hypothesizedthat the high SvO2 found may also be due to defective oxygen utilization at the mitochondrial level.

We therefore studied mitochondria in affected muscle tissue from amputated

limbs of CRPS I patients. We observed that mitochondria obtained from CRPS I muscle tissue displayed reduced mitochondrial ATP production and substrate oxidation rates in comparison to control muscle tissue. It remains to be established if the mitochondrial dysfunction that is apparent at the end-stage of CRPS I is also present in earlier stages of the disease, or are secondary to CRPS I. The observation of a reduced mitochondrial energy production combined with reactive oxygen species induced damage in muscle tissue from CRPS I patients warrants further studies into the involvement of mitochondrial dysfunctioning in the pathophysiology of CRPS I.

Therefore we are interested to study the mitochondrial energey production system in patients with acute CRPS I of the lower extremities by means of muscle biopsy. The contra lateral not involved extremity may function as control value.

Study objective

Does mitochondrial dysfunction play an important role in the pathofysiology of patients with Complex Regional Pain Syndrome Type I ?

Study design

Patient inclusion period of 12 months, in total six patients are included

Analysis of data: 6 months

Presentation and publication in an peer reviewed English Journal

Study burden and risks

Muscle biopsie is an accepted method for analysis and diagnosis of muscle disorders

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

- Acute CRPS I of one lower extremity
- Diagnosis of CRPS I by Bruehl criteria
- Age > 18 years

Exclusion criteria

- Patients treated with oxygen radcial scavengers
- Pregnancy
- No informed Consent
- Use of medication (antihypertensive medication)
- Previous CRPS I of one extremity
- CRPS I due to automutilation
- Nerve damage as cause (CRPS II)

Study design

Design

Study type: Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2012
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	23-08-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL36393.091.11