Central aspects of fixed dystonia in patients with Complex Regional Pain Syndrome

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• To investigate if FD in CRPS is associated with specific structural and functional changes of the brain.• If so, to find out which of these changes are specific for FD in CRPS, i.e., independent regardless the clinical setting (pain versus...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational invasive

Summary

ID

NL-OMON36353

Source
ToetsingOnline

Brief title
central aspects of fixed dystonia

Condition

- Movement disorders (incl parkinsonism)

Synonym
tonic dystonia in reflex sympathetic dystrophy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: central nervous system, CRPS, fixed dystonia, MRI

Outcome measures

Primary outcome

Gray matter volume

Anisotropy white matter

gray-white matter connectivity

activity brain areas

Secondary outcome

Pain scores

Psychiological score

Dystonia score

Study description

Background summary

Complex Regional Pain Syndrome (CRPS) is a very disabling syndrom with an incidence of 26 per 100,000 people in the Netherlands, more common in women than in men. Ninety percent of the patients develop symptoms after peripheral trauma. Patients complain of constant severe pain that is aggravated when in contact with non-painful stimuli (allodynia). Other symptoms develop such as fluctuations in color and temperature, changes in nail and hair growth and movement disorders like fixed dystonia (FD).
FD is common in CRPS and develops in 20% of patients. It is characterized by a flexed and inversed state of the affected limb. The symptoms may arise soon after CRPS started but can also develop months or years later. This is one of the major reasons for the ongoing discussion on the etiology of this condition and the relationship with CRPS. Many researchers think that this form of dystonia is of psychological origin and is not maintained by a biological substrate.
Indications for an underlying biological substrate are found in some imaging studies in CRPS patients focussing on structural and functional changes and

recent research focussing on cortical disinhibition in patients with FD
These studies highlight prominent changes in sensorymotor supraspinal circuitry in both CRPS and FD patients. Until now, no differentiation has been made between these two syndromes in terms of structural and functional differences seen in the brain. Therefore we will compare patients with CRPS with and without FD, FD without CRPS and controls on the following parameters: Cortical plasticity expressed by gray and white matter volume change using Voxel Based Morphometry (VBM), white matter directionality and connectivity using Diffusor Tensor Imaging (DTI), brain activity in rest using resting state fMRI (rfMRI) and heat pulse evoked fMRI

Study objective

• To investigate if FD in CRPS is associated with specific structural and functional changes of the brain.
• If so, to find out which of these changes are specific for FD in CRPS, i.e., independent regardless the clinical setting (pain versus spontaneous onset) in which FD has developed.

Study design

case-controled

Study burden and risks

none

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

3 groups:
1: CRPS with fixed dystonia. fulfil 'Budapest criteria' CRPS. Fixed dystonia in one or more upper limbs
2: CRPS without dystonia: fulfil Budapest criteria'. 3: Fixed dystonia in one or more upper limbs

Exclusion criteria

all: <18 years old. Positive scan-exclusion criteria, disease or lesions in central nervous system, psychiatric history
group:
1: mobile dystonia, genetic form of dystonia, symptoms in lower limbs, drug delivery pump
2: dystonia, symptoms in lower limbs, drug delivery pump
3:CRPS

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2011
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	12-07-2011
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	NL34614.058.11