The relationship between pain and cognitive functioning, of patients with neurodegenerative diseases such as Parkinson's disease, Multiple Sclerosis and Huntington's disease Substudy: The relationship between pain, cognitive functioning, and motor activity in patients with multiple sclerosis

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Various brain areas play a crucial role in both pain and cognition, supporting the existence of a close relationship between pain and cognition. Consequently, it is important to examine whether pain experience changes at the moment the patient shows...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neurological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON44950

Source ToetsingOnline

Brief title

Pain and cognition in neurodegenerative diseases;Substudy: Pain and cognition in patients with Huntington's disease

Condition

- Neurological disorders NEC
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Synonym disorders of the central nervous system

Research involving Human

Sponsors and support

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

Intervention

Keyword: cognition, motor activity, neurodegenerative diseases, pain

Outcome measures

Primary outcome

The primary study parameters are cognition, pain, motor activity and the

relationship between pain, motor activity and cognition.

Secondary outcome

The secundary study parameters are the extent one suffers from depressions and

anxiety, activities of daily life (ADL) and the sleep-wake rhythm. Both pain

and cognition may be influenced by or may have an effect on these variables.

Study description

Background summary

Parkinson*s disease, multiple sclerosis, and Huntington*s disease are neurodegenerative disorders which are characterized by degeneration of the white and grey matter. Besides sensory, motor, and cognitive disturbances, is also pain a clinical hallmark of these disorders. Unfortunately, in these specific disorders pain is not acknowledged as an important clinical symptom, resulting in a less effective treatment of pain. However, in general the extent in which people suffer from pain is crucial for the quality of life as it has a large impact on for example work and personal relationships. Without an effective pain treatment one can get isolated, anxious or depressive.

Study objective

Various brain areas play a crucial role in both pain and cognition, supporting the existence of a close relationship between pain and cognition. Consequently, it is important to examine whether pain experience changes at the moment the patient shows signs of a cognitive deterioration. A relationship between pain experience and cognitive functioning has not been examined in the above mentioned three neurodegenerative disorders so far. This is remarkable as insight into this relationship is relevant for effective pain treatment. From a theoretical point of view, one may assume that an increase in white matter lesions coincides with an increase in the experience of pain. Due to an increase in cognitive impairment, the patient may become less able to communicate about his/her pain. Therefore, this study is of clinical relevance.

In patients with MS, also the relationship between pain, cognition, and motor activity will be examined.

Study design

The total study (Parkinson, MS, Huntington) will include 284 patients and 170 controls without neurodegenerative disorders. In the past 10 years we performed a number of studies in which we examined pain and cognition in patients with dementia (Alzheimer's disease, vascular dementia). The power-analysis was based on the results of these studies. Participants will be attracted through outpatient clinics neurology, pateints'associations, and general practitioners. Global cognitive functioning will be testen by means of the Mini-Mental State Examination. More specific cognitive functions (attention, memory, executive functions) will be tested by a neuropsychological testbattery. Motor activity will be assessed by two scales. Pain experience will be assessed by means of a number of pain scales that address pain intensity and the motivational-affective aspects of pain.

In the MS-study, 40 new patients will be included. In these patients, motor activity will be examined by two tests: the Expanded Disability Status Scale (EDSS) and the Multiple Sclerosos Functional Composite (MFSC) (see protocol).

The total number of patients plus controls will amount: 454 (284 patiënts, 170 controls).

In patients with Huntington's disease also a pain observation scale will be applied. In addition, the test Trailmaking will be replaced by the Key-Search task of the Behavioural Assessment of Dysexecutive Disorders.

Study burden and risks

This study encompasses no risks for the patients. It is possible, however, that the patients become tired during testing. We will address this point carefully and extensively with the patients (and legal representatives) at the onset of the examination. It will always be possible to complete the examination in two or three sessions. This important aspect of the examination will have our full attention.

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

-communicative -cooperative

Exclusion criteria

-history with stroke, focal brain abnormalities, psychiatric disorders (e.g. depression), alcohol abuse

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	13-05-2008
Enrollment:	454
Туре:	Actual

Ethics review

Approved WMO	27 11 2007
Date.	27-11-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	28-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

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Date:	08-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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 NL19801.029.07