Pain processing and pain assessment in Huntington*s disease
A pilot study

Published: 03-07-2024
Last updated: 27-12-2024

The main objective of this pilot study is to assess the feasibility of internationally agreed pain test batteries in order:- To measure the overall facial response to pain in patients with HD- To explore the psychometric properties (inter- and...

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

Summary

ID

NL-OMON56873

Source
ToetsingOnline

Brief title
Huntington*s Disease and pain

Condition

- Movement disorders (incl parkinsonism)

Synonym
Huntington's Disease and pain

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: European Huntington's Disease Network

Intervention

Keyword: Huntington's Disease, Pain, Pain assessment, Pain processing

Outcome measures

Primary outcome

The feasibility of the different pain test batteries will be evaluated using a screening tool including different items and cut-off scores.

Secondary outcome

The potential disturbances in the processing of pain in terms of facial expression will be measured by the investigators by using the facial expression items of the PAIC15. In addition, the intra- and interrater reliability of the facial descriptors, body movements and vocalization items of the PAIC15 will be assessed.

An exploratory objective is to assess the agreement (measurement error), in other words how close scores for repeated measures are, will be assessed for each outcome included in this study (e.g. facial response [PAIC15], pain inhibition and facilitation).

Study description

Background summary

Huntington*s Disease (HD) is a autosomal-dominant neurodegenerative disease causing motor (e.g., chorea) and non-motor symptoms (e.g., neurocognitive and neuropsychiatric disturbances, and autonomic disturbances). Pain is a commonly reported non-motor symptom in HD, with a prevalence of around 40% in the manifest stage. Despite its high prevalence, patients with HD seem to be at risk for undertreatment of pain as the disease progresses. This might be caused by disturbances in the pain processing, which might influence the pain experience and subsequently also the use of analgesics. Available experimental

studies in HD demonstrated indeed a significant prolongation of processing noxious stimuli at spinal cord level in the manifest stage, compared to healthy controls and individuals in the premanifest stage.
Pain management regimens rely on adequate pain assessment using valid and reliable pain scales. Despite the availability of specifically developed and internationally agreed pain test batteries to test disturbances in pain processing and psychometric properties of pain scales, studies concerning these topics in HD are scarce. In order to test the effect of HD on pain processing and the psychometric properties of pain scales, the different pain test batteries should be assessed on their feasibility in HD.

Study objective

The main objective of this pilot study is to assess the feasibility of internationally agreed pain test batteries in order:
- To measure the overall facial response to pain in patients with HD
- To explore the psychometric properties (inter- and intrarater reliability) of the facial descriptors, body movements, and vocalization items of an observational pain scale, the Pain Assessment in Impaired Cognition Scale (PAIC15), in patients with HD.
- To explore the prevalence and extent of endogenous pain modulation in the early and middle stage of HD (facilitation, inhibition and the balance between the two).
An exploratory objective is to assess the agreement (measurement error), in other words how close scores for repeated measures are, will be assessed for each outcome included in this study (e.g. facial response, pain inhibition and facilitation).

Study design

An experimental, observational, cross-sectional study.

Study burden and risks

This study assesses the feasibility of internationally agreed pain test battery, which will eventually provide the possibility to assess whether disturbances in pain processing in HD are present and to test the psychometric properties of an observational pain scale (PAIC15). The development of a reliable pain scale and gaining fundamental knowledge about pain processing in HD yield benefits for pain management regimens in HD.
The risk associated with this study is small and related to the discomfort associated with the pain test batteries. The experimental setups are frequently used and according to internationally agreed standards. In addition, the devices used for inducing a painful stimulus will be set according to the safety limits so that no physical harm can be inflicted on the patients.
The experimental setup allows us to collect unique data concerning pain

processing and psychometric properties of a pain scale in HD. Furthermore, the combination of experimental data with clinical data results in a positive balance of benefits compared to the small risk of this study.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, an Adult- Onset Huntington's Disease (HD) subject must meet the following criteria:
1. Genetically and clinically confirmed AoHD patients (>= 21 years, CAG repeats >= 36; DCL of 4).
2. Good general health apart from having HD.
Note: Patients with chronic illness (e.g. hypertension) will be eligible if the illness is stable and well-controlled according to the investigator that will

not impact the primary objectives of the study.
3. Able to give written informed consent.

Exclusion criteria

Potential Adult-Onset Huntington's Disease subject who meets any of the following criteria will be excluded from participation of this study:
1. Juvenile and Pediatric Huntington*s Disease (age at onset <21 years).
2. Patients in the late stage of the disease (UDHRS-TFC score < 3).
3. Have medical, psychiatric, or other conditions (other than HD) that, according to the investigator, may compromise the patient*s ability to understand the patient information sheet, to give informed consent, to comply with all study requirements, or to perform study assessments .(other than HD).
4. Have a history of (in the past year) or current (ab)use of any drug, alcohol or medication that, in the opinion of the investigator, may seriously impact interfere with the primary objectives of the study, according to the investigator.
5. The presence of any sensorimotor neuropathy or any another disturbance significantly disturbing the somatosensory systems), based on medical history and/or clinical examination, that can interfere with the pain testing battery.
6. Women who are pregnant or breastfeeding.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO Date:	03-07-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL84512.058.23