Track-HD

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

Summary

ID

NL-OMON31178

Source
ToetsingOnline

Brief title
Track-HD

Condition

- Movement disorders (incl parkinsonism)

Synonym
Huntington's disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,High-Q Foundation;New York;VS

Intervention

Keyword: Biomarkers, European network, Huntington's disease, Longitudinal

Outcome measures

Primary outcome

All variables are considered to be primary study parameters: clinical, MRI,

genetics and biomarkers to determine which combination is the most sensitive to

detect changes in the natural course of HD.

Secondary outcome

Dependant on results on the primary outcome variables.

Study description

Background summary

Huntington*s disease (HD) is an autosomal dominant neurodegenerative disorder that results from an unstable expansion of the trinucleotide repeat CAG in the HD gene IT-15. HD has a prevalence of 5-10 per 100,000 in the general population. The clinical features of HD usually emerge in adulthood (mean age of 40 years) with a movement disorder, cognitive dysfunction and psychiatric symptoms. The course of HD is relentless, leading to functional disability and death over a period of 10-30 years. With genetic testing (following genetic counseling) it is possible to predict that a person will develop HD a long time before clinical symptoms and signs develop. To date, there is no treatment that has been shown to alter the progression of the disease. Benefical effects have been reported when applied in model systems of HD but the predictive value of these results for patients are unknown. A more seamless integration of basic and clinical HD research is required to conduct future clinical studies, e.g. by identifying biological markers that track the course of HD and by identifying factors that influence the onset and progression of illness.

Study objective

Track-HD is designed to relate phenotypic characteristics in as many modalities as can be measured (clinical, cognitive, quantitative motor, oculomotor, neuropsychiatric, imaging, laboratory) and genetic factors, in order to relate phenotypic characteristics, genetic factors (*genetic modifiers*), data derived from the study of blood (*wet biomarkers*) and imaging data (*dry biomarkers*). The primary objective of this study will therefore be to determine what combination of measures is the most sensitive for detecting change over the

natural course of HD, with a view to validating these measures for use in future therapeutic trials.

Study design

All subjects will be assessed at baseline, 1 year and 2 years. At each visit, subjects will undergo clinical, motor, cognitive, neuropsychiatric, MRI and oculomotor assessment as well as donating blood samples.
Shorter time interval assessments may be instituted following the one-year data analysis if there is evidence for robust change over one year in any assessment. Updates to the assessment protocol will occur annually or sooner if needed so that new methods and findings can be dynamically incorporated to enhance the design and usefulness of the study.

Study burden and risks

Since Track-HD is an observational study, participants do not undergo specific risks by participating. The assessments take almost one day but their burden will be limited to a minimum, with extra breaks and help in relaxing for blood drawning and MRI scans if needed.
Participants will receive no immediate benefit from participation in this study. The only potential benefit is a better understanding of HD and the possibility that the information obtained in this study lead to potential treatments and to plan future research studies of experimental drugs aimed at slowing disease progression or postponing the onset of HD.

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

• Ability to tolerate MRI and sample donation;• Subjects will be either:
1. Control subject
a. Partner/spouse of a patient, not at risk of HD
b. Known non-carriers for HD (after genetic testing);2. Premanifest gene carrier
a. Positive genetic test with CAG repeat length >= 40 and
b. Burden of pathology score [(CAG-35.5) × age] >250 and
c. Absence of diagnostic motor features according to the UHDRS 99;3. Early HD
a. Positive genetic test with CAG repeat length >= 40 and
b. Presence of diagnostic motor features according to the UHDRS 99 and
c. Shoulson and Fahn stage 1 (TFC > 9-13) or 2 (TFC >= 7) according to the UHDRS 99 - functional capacity

Exclusion criteria

• Stage 3 (TFC <= 6) or greater at time of enrolment
• Less than 18 years of age
• More than 65 years of age
• Major psychiatric disorder at time of enrolment
• Concomitant significant neurological disorder
• Concomitant significant medical illness
• Unsuitability for MRI, e.g. claustrophobia, metal implants
• Unwillingness to donate blood
• History of significant head injury
• Drug and/or alcohol abuse
• Significant hand injuries that preclude either writing or rapid computerized responding
• Currently participating in a clinical drug trial

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:	Recruitment stopped
Start date (anticipated):	23-03-2008
Enrollment:	90
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	NL18769.058.07