A control cohort for patients with movement disorders

Published: 03-05-2010
Last updated: 04-05-2024

To set up a control group with the aim to obtain reference values that allow for comparisons with data of patients with movement disorders.

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

Summary

ID

NL-OMON33191

Source
ToetsingOnline

Brief title
Control cohort movement disorders

Condition

- Movement disorders (incl parkinsonism)

Synonym
dystonia, Parkinson

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Ministerie van Economische Zaken

Intervention

Keyword: cohort, control subjects, movement disorders

Outcome measures

Primary outcome

Differences between patients with movement disorders and controls with respect to autonomic dysfunction, physical features, personality traits, depression, traumatic experiences and recent life events. Additionally, genetic differences between both groups.

Secondary outcome

None

Study description

Background summary

The department of neurology follows several cohorts of patients with movement disorders, that is, patients with Parkinson*s disease, tonic dystonia and complex regional pain syndrome related dystonia, for which a proper control group currently is not available. The present proposal describes the set-up of a cohort of control subjects in whom data will be collected that will be compared to those of patients. Reference values obtained from controls are important to determine if findings in patients fall in the range of normal values; differences in comparison to controls may provide hints for potential causal mechanisms or signal significant co-morbidities. Two-hundred subjects will be invited to complete questionnaires (either online or on paper) evaluating constructs that are relevant for comparison with one or more of the aforementioned patient groups and include depression, autonomic dysfunction, somatoform dissociation, early traumatic experiences, recent life events, personality traits and REM sleep behavioural disorder. Data will be entered in a ProMISe© database and maintained by the department of Medical Statistics of the LUMC. This database will contain indirectly identifiable subject data only. Additionally, 20 cc of blood will be collected in 1200 subjects for DNA isolation. This is necessary to examine if genetic differences exist between patients and controls; such differences could provide indications for potentially involved biological pathways and hopefully ultimately lead to more

effective treatments for patients with these conditions. Subjects are also asked if they give consent to be approached for other future research purposes.

Study objective

To set up a control group with the aim to obtain reference values that allow for comparisons with data of patients with movement disorders.

Study design

The present proposal involves the set up of a control cohort that allows for case-control comparisons.

Study burden and risks

The completion of the questionnaires will take approximately one hour. Further, 2 tubes of blood (20 cc) will be drawn. There are no risks or benefits involved.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Male and female subjects aged 18 years or older who give informed consent to store their data and have their blood drawn.

Exclusion criteria

Diseases of the central nervous system; anxiety; depression; conditions associated with pain and/or limited function of the neck, back or extremities.

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-05-2010
Enrollment:	1200
Type:	Actual

Ethics review

Approved WMO Date:	03-05-2010
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	NL29235.058.09