Transcranial sonography in Parkinson*s Disease and Restless Legs Syndrome

Published: 29-10-2008
Last updated: 18-07-2024

We will perform a study to describe the echogenicity of the substantia nigra, red nucleus and brainstem raphe in PD patients with and without RLS, RLS patients without PD and healthy controls. The echogenicity will be correlated with the the serum...

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

Summary

ID

NL-OMON32740

Source
ToetsingOnline

Brief title
TCS in PD and RLS

Condition

- Movement disorders (incl parkinsonism)

Synonym
animarum tibiarum, Ekbom syndrome, restless legs

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden
Source(s) of monetary or material Support: nvt;er is geen geldstroom voor dit onderzoek

Intervention

Keyword: Parkinson's Disease, Restless Legs Syndrome, substantia nigra, Transcranial sonography

Outcome measures

Primary outcome

To determine the echogenicity of the substantia nigra, red nucleus and brain

stem raphe in these four groups

Secondary outcome

To determine the serum iron status in these four groups

To determine the relation between echogenicity and iron status in the four

groups

Study description

Background summary

Restless Legs syndrome (RLS) and Parkinson*s disease (PD) share possible pathogenic aspects. The most important aspect is that the two disorders can be treated with dopamine medication although PD shows neurodegeneration of the neuromelanine cells in the substantia nigra (SN) which is not found in RLS.
In the two clinical very different disorders also other distinct aspects are found.
In sonography studies, the substantia nigra (SN) is found to be hyperechogenitic in PD patients and hypoechogenetic in RLS patients.Animal and postmortem studies provided evidence that the hyperechogenicity of the SN in PD patients is related to increased iron levels of the SN. The exact cause of the iron accumulation in the SN in PD patients is unknown and it is also unknown whether the iron accumulation in PD is a primary or secondary phenomenon.
As significant lower iron concentrations are found in neuropathological studies and magnectic resonance imaging in the SN of RLS patients the hypoechogenicity of the SN in RLS patients is hypothesised to be the result of iron deficiency in the SN of RLS patients. Several studies showed that iron deficiency in RLS patients appear to produce a dopamine dysfunction that may involve disruption of synaptic function resulting in impairing the circadian regulation of dopamine in RLS patients.

Recently it is shown that PD patients with RLS have lower serum ferritine levels compared to PD patients without RLS. Sonography studies in RLS patients also showed a hyperechogenicity of the nucleus ruber (NR) and hypo-echogenicity of the Brain raphe (BR) compared to healthy controls.

Study objective

We will perform a study to describe the echogenicity of the substantia nigra, red nucleus and brainstem raphe in PD patients with and without RLS, RLS patients without PD and healthy controls. The echogenicity will be correlated with the the serum iron status of the study population to investigate if there is an association between the iron-status, especially the ferritin levels, and the echogenicity of the substantia nigra.

Study design

This cross-sectional study is part of an ongoing longitudinal cohort study, the PROfiling PARKinson*s disease (PROPARK) study.

Study burden and risks

Since the TCS is a non-invasive technique there are no risks for the subjects. There is a risk factor to develop a haematoma when performing a blood tap. There is some burden, especially for the PD patients, to make the trip to the hospital.

Contacts

Public
Medisch Centrum Haaglanden

lijnbaan 32
2501 CK Den Haag
Nederland
Scientific
Medisch Centrum Haaglanden

lijnbaan 32
2501 CK Den Haag
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria PD patients with RLS
1.Fulfillment of the United Kingdom PD Society Brain Bank criteria for idiopathic PD.
2.Definite RLS in which all four revised minimal criteria of RLS are fulfilled based on an personal history taken by a RLS trained investigator/ doctor;Inclusion criteria PD without RLS
1.Fulfillment of the United Kingdom PD Society Brain Bank criteria for idiopathic PD.
2.Definite no diagnosis of RLS based on a personal history taken by a RLS trained investigator/ doctor
3.Age, sex , PD severity (Hoehn & Yahr and total levodopa-equivalent) matched to the PD patients with RLS;Inclusion criteria of RLS without PD
1.Definite RLS in which all four revised minimal criteria of RLS are fulfilled based on an personal history taken by a RLS trained investigator/ doctor
2.All secondary RLS patients are excluded besides iron deficiency related RLs
3.Age and sex matched to the PD patients;Inclusion criteria healthy controls
1. Definite no RLS or other known diseases
2. Age and sex matched to the RLS patients without PD

Exclusion criteria

1.No temporal bone window to perform a qualitatively good transcranial sonography
2.Iron medication
3.Pregnancy

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):	01-09-2008
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	29-10-2008
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	NL24129.098.08