European database of [123I]FP-CIT (DaTSCAN) SPECT scans of healthy controls (ENC-DAT)

Published: 14-01-2008
Last updated: 10-05-2024

The ultimate goal is to build a large, well-documented, database of normal FP-CIT data obtained in healthy volunteers. For this purpose, in a large number of European institutes we will obtain in, minimal 10 and maximal 15 healthy volunteers per...

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

Summary

ID

NL-OMON31957

Source
ToetsingOnline

Brief title
ENC-DAT

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,EANM,GE Healthcare

Intervention

Keyword: dopamine transporter, FP-CIT SPECT, healthy controls

Outcome measures

Primary outcome

variation in dopamine transporters

Secondary outcome

na

Study description

Background summary

Nowadays, it is feasible to detect or exclude dopaminergic degeneration in humans in vivo with the registered radioligand [123I]FP-CIT (DaTSCAN) and SPECT. Since several years, FP-CIT SPECT can be used routinely to differentiate disorders characterized by dopaminergic degeneration (e.g., Parkinson*s disease; PD) from disorders not characterized by degeneration (e.g., essential tremor), but which could show some overlap in clinical symptomatology. Recently the technique has been registered to differentiate dementia with Lewy bodies from Alzheimer*s disease.
In routine clinical studies, FP-CIT SPECT scans are often evaluated visually. However, a few studies showed that a quantitative assessment may be more adequate. To perform a quantitative analysis it is essential, however, to have entry to a database of normal reference data. Ideally, these data will be obtained in a large group of healthy volunteers. However, for the majority of departments that use FP-CIT SPECT routinely, it is not feasible to build a huge database on there own and fast. This problem has been recognized by the European Association for Nuclear Medicine (EANM). Recently, the neuroimaging committee of the EANM has taken the initiative to build up a database in a collaboration of 15 European institutes, including the AMC. The aim of this collaboration is to build up the database (n=175), which will be available for all departments that are using FP-CIT SPECT for routine clinical studies. The big advantage of this approach it that, because a large group of institutes support this initiative (15 in total), a relative small group of volunteers has to be scanned within each institute to build up a large and well-documented database over a reasonable time.

Study objective

The ultimate goal is to build a large, well-documented, database of normal FP-CIT data obtained in healthy volunteers. For this purpose, in a large number of European institutes we will obtain in, minimal 10 and maximal 15 healthy volunteers per center, two FP-CIT SPECT scans per participant.

Study design

Normal FP-CIT data will be obtained in healthy volunteers. For this purpose, in a large number of European institutes we will obtain in, minimal 10 and maximal 15 healthy volunteers per center, two FP-CIT SPECT scans per participant.

Study burden and risks

The burden for each participant consists of exposures to each of the following: one [123I]FP-CIT injection (2 SPECT scans will be obtained after injection), one standard MRI scan, one neurological and neuropsychiatric examination, and delivery of one urine specimen (to exclude recent use of drugs of abuse). For females from child bearing age, a urine test will be performed to exclude pregnancy.
The risks for the participants are: radiation burden (within the WHO criteria for research in human).

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy (20-90 years)

Exclusion criteria

- A family member in the first line with parkinsonism
- Consaguineous spouses of PD patients
- Deviation found after clinical neurological exam or by neuropsychiatric screening
- MMSE < 28
- Contra-indication to participate for MR research (e.g., pacemaker)
- Structurel abnormality detected by MRI (for potential participants * 60 yrs, hyperintensities in the white matter on T2-weighted images will be judged as normal)
- Participated in experimental research during the last year in which the radiation burden was more than 1 mSv.
- Suffering from a severe non-neurological disease (including diabetes, heart diseases, lung-, liver, thyroid or kidney-disease)
- A medical history of a neurological or psychiatric disease (including depression, bipolair disorder, alcohol or drugs addiction)
- Use of drugs which are known to influence the [123I]FP-CIT scan (e.g., amphetamines or antidepressants)
- Pregnant or lactating females

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	ID
CCMO	NL20343.018.07