Specific binding in striatum and semi-quantification of the Single Photon Emission Computed Tomography tracer [I-123]-FP-CIT in healthy volunteers.

Published: 19-02-2007
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Collecting normal values of I-123-FP-CIT uptake with SPECT in striatum relative to occipital cortex uptake in heathy volunteers

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

Summary

ID

NL-OMON29912

Source
ToetsingOnline

Brief title
Normal binding of FP-CIT.

Condition

- Movement disorders (incl parkinsonism)

Synonym
Paralysis Agitans, Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: [I-123]-FP-CIT, healthy volunteers, Parkinson's disease, SPECT

Outcome measures

Primary outcome

123I-FP-CIT striatum/occipitaal uptake ratio

Secondary outcome

not applicable

Study description

Background summary

I-123-FP-CIT Single Phothon emission tomography (SPECT) is used for the diagnosis of M.Parkinson. Patients with M.Parkinson have a decreased uptake of I-123-FP-CIT.

For the optimal use of I-123-FP-CIT SPECT normal values of I-123-FP-CIT uptake in the striatum relative to the occipital cortex are necessary.

Study objective

Collecting normal values of I-123-FP-CIT uptake with SPECT in striatum relative to occipital cortex uptake in heathy volunteers

Study design

Measurement of I-123-FP-CIT uptake with SPECT in 32 healthy volunteers (16 male/ 16 female subjects)

Study burden and risks

Risks and burden associated with study for volunteers:
1) single intravenous injection
2) duration of studyprotocol: 40-60 minutes SPECT scan , 3 hours waiting time between injection of tracer and start SPECT scan
3) radiation; this SPECT scan results in a radiation dose of 4,44 milliSievert

(mSv) (for the standard dose of 185 MBq I-123-FP-CIT), the normal radiation dose in the Netherlands is 2,5 mSv/year.
4) minimal risk of bleeding during intravenous administration of the tracer I-123-FP-CIT.
5) there is no direct benefit for the healthy volunteer. there is only a public interest : improvement of diagnosis of M.Parkinson patients .

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

healthy volunteer

Exclusion criteria

use of medication

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):	09-01-2006
Enrollment:	32
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	NL12807.029.06