[123I] iodobenzamide single photon emission computer tomography of D2 receptors in obsessive-compulsive spectrum disorders

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The primary goal of the proposed study is to investigate the dopamine D2 receptor binding potential in patients with body dysmorphic disorder (BDD) and patients with trichotillomania (TTM) in comparison to healthy subjects. As BDD and TTM are OC...

Ethical review	Approved WMO
Status	Pending
Health condition type	Anxiety disorders and symptoms
Study type	Observational invasive

Summary

ID

NL-OMON34081

Source
ToetsingOnline

Brief title
SPECT imaging in OC spectrum disorders

Condition

- Anxiety disorders and symptoms

Synonym
dysmorphophobia, hair pulling disrder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: neuroimaging, OC spectrum disorders, SPECT

Outcome measures

Primary outcome

Primary study parameter is the total number of striatal D2 receptors. A ratio

will be calculated of radio-activity counts in the ROIs (striatal activity)

compared to the reference region (cortical activity).

Secondary outcome

no secundary study parameters

Study description

Background summary

Body dysmorphic disorder (BDD), also known as dysmorphophobia, consists of preoccupation with an imagined defect of the appearance. Trichotillomania is a disorder characterized by repetitive hair pulling, leading to noticeable hair loss and functional impairment. Both disorders belong to the obsessive-compulsive spectrum disorders and there is evidence suggesting dopaminergic abnormalities in BDD and TTM. No neuroimaging research did already involve the dopaminergic system in patients with BDD and TTM.

Study objective

The primary goal of the proposed study is to investigate the dopamine D2 receptor binding potential in patients with body dysmorphic disorder (BDD) and patients with trichotillomania (TTM) in comparison to healthy subjects. As BDD and TTM are OC spectrum disorders it is hypothesized that the mean D2 receptor binding potential will be significantly lower in patients with BDD and TTM compared to the comparison subjects. Because different allelles of the dopamine receptor are involved in density and functional capacity of the dopamine receptor, frequencies of the allelles of the dopamine receptor will be analyzed

in a blood sample.

Study design

An open, single dose study with 10 BDD patients, 10 TTM patients and 10 healthy controls. The binding patterns of the radiolabeled IBZM will be investigated with SPECT. Multi-modality imaging analysis will be used to define regions of interest (ROIs) on the SPECT on the basis of a co-registered anatomic MRI-scan. The radio-activity counts in the ROIs (striatal activity) will be used to calculate ratios between the ROIs and the reference region (cortical activity). The results of a previous study "IBZM single photon emission computed tomography (SPECT) of dopamine D2 receptors in obsessive compulsive disorder" at the University Medical Center Utrecht will be used for a comparison with patients with obsessive compulsive disorder.

Study burden and risks

The radioligand 123I-IBZM, to be administered intravenously, is registered in The Netherlands as radio-pharmaceutical. Until now no undesirable effects of this radio-pharmaceutical were reported. The thyroid of the subject will be blocked with potassium iodide in an oral dosage of 200 mg per day, starting 2 days prior to and on the day of administration of 123I-IBZM. The effective dose equivalent (EDE) of 123I-IBZM is 0.034 mSv/MBq for an adult when using saturated potassium iodide drops to block the thyroid. Therefore the total ED for subjects participating in the study is expected to be no more than 6.0 mSv, placing them in category IIb of the WHO (ICRP60).
Furthermore, two blood samples (2x 7cc) will be taken in order to determine the genotype of the dopamine D2 region for each patient. Also, a MRI scan will be performed. In case of brain abnormalities, patients will be informed and if necessary adequate treatment will be started.

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

Inclusion criteria: BDD patients and TTM patients:
- Physically healthy subjects
- Male and female, aged between 18-65 years
- Diagnosis of BDD by DSM -IV criteria, confirmed by the Structured Clinical Interview of DSM-IV
- Able to provide written informed consent and to comply with all study procedures.;Inclusion criteria: Control group
- Physically healthy subjects
- Male and female, aged between 18-65
- Absence of psychiatric DSM-IV axis I disorders, confirmed by the Structured Clinical Interview of
DSM-IV Axis Diagnoses (SCID)
- Absence of psychiatric DSM-IV axis II disorders, confirmed by the Structured Clinical Interview of
DSM-IV Axis Diagnoses (SCID)
- Able to provide written informed consent and to comply with all study procedures.

Exclusion criteria

Excusion criteria: BDD patients and TTM patients:
- Comorbidity of DSM-IV axis I disorders. In case of depressive symptoms, the score on the Hamilton Depression Rating Scale (HDRS) should be less then 16
- Comorbidity of DSM-IV axis II disorders in cluster A or B ;Exclusion criteria: General
- Currently participating in an investigational study, or having participated in such a study within 30

days of their enrollment.
- Use of psychotropic medication within four weeks before the first test day.
- Drug or alcohol-abuse over a period of three weeks prior to the experiment. More then 15 cigarettes and more then 6 cups of caffeine containing coffee, cola or tea.
- A history of neurological illness or other medical problems potentially having central nervous
system sequellae.
- Pregnancy, breast feeding and use of inadequate anticonception.
- Use of other medication potentially influencing cerebral blood flow.
- Ongoing psychotherapy. Behavioral psychotherapy must be discontinued at least three months
before the first test day.
- Contraindications for MRI scan (claustrofobia, inclusion of metal components in the body, e.g.
pacemaker)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2010
Enrollment:	30
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	NL33001.018.10