Effects of social exclusion on dopamine function in the human brain. An [123I]Iodobenzamide SPECT study in young adults with serious hearing impairment.

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To test the following hypotheses:1. The baseline [123I]IBZM binding potential ([123I]IBZM-BP) in the ventral striatum is smaller in patients with SAHI than in healthy subjects, due to increased baseline activity of the mesolimbic dopamine system. 2...

Ethical review	Approved WMO
Status	Pending
Health condition type	Schizophrenia and other psychotic disorders
Study type	Observational invasive

Summary

ID

NL-OMON32473

Source
ToetsingOnline

Brief title
Social exclusion and dopamine function in humans

Condition

- Schizophrenia and other psychotic disorders

Synonym
psychosis, schizophrenia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Stichting J.M.C. Kapteinfonds;p/a Dhr. S. Janssen; Craijenesterlaan 47 Haarlem

Intervention

Keyword: deafness, dopamine, psychosis, social exclusion, stress

Outcome measures

Primary outcome

The decrease in [123I]IBZM-Binding Potential after amphetamine challenge.

Secondary outcome

The baseline [123I]IBZM binding potential ([123I]IBZM-BP)

Study description

Background summary

According to the social defeat hypothesis the long-term experience of social exclusion or social defeat leads to enhanced baseline activity and/or sensitization of the mesolimbic dopamine (DA) system and puts the individual at increased risk for psychotic disorder and/or schizophrenia. This pilot study tests the hypothesis by comparing DAergic function in two groups who are expected to differ greatly: (1) young adults with a severe, acquired hearing impairment (SAHI) who cannot participate in conversations and feel socially excluded; (2) healthy peers.

Study objective

To test the following hypotheses:
1. The baseline [123I]IBZM binding potential ([123I]IBZM-BP) in the ventral striatum is smaller in patients with SAHI than in healthy subjects, due to increased baseline activity of the mesolimbic dopamine system.
2. The decrease in [123I]IBZM-BP after amphetamine challenge is significantly greater in patients with SAHI than in healthy subjects.
3. There is a greater psychological/behavioural response to amphetamine (happiness, restlessness, increased level of energy) in subjects with SAHI than in healthy subjects.

Study design

Comparison of 15 subjects with Severe Acquired Hearing Impairment to 15 healthy subjects.
Subjects will be examined using SPECT-imaging with the D2 tracer [123I]iodobenzamide.
In one session, baseline D2 receptor binding and endogenous DA release after stimulation with D-amphetamine sulphate (0.3 mg/kg iv) will be assessed (bolus/constant infusion technique). Patients and healthy subjects will be matched for age, sex and smoking status.

Study burden and risks

The study includes two visits: 1. Screening 2. Investigation.

During the investigation subjects will receive an intravenous infusion in each arm and have to lie still in scanner, for 2 x 50 minutes.

The effective dose for the whole SPECT study is approximately 6.1 mSv, which is within an acceptable range for healthy volunteers.

The major somatic side effects of amphetamine infusion are cardiovascular (hypertension, palpitations, tachycardia, orthostatic hypotension).
The psychological/behavioral effects of amphetamine are increased level of alertness, talkativeness, agitation, mood changes and anxiety. These effects are transient and, at this dose, well tolerated.

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

1. Patients: severe acquired hearing impairment, which impedes normal conversation and age 18-25 years.
2. Healthy subjects: age 18-25 years.

Exclusion criteria

Presence of psychotic disorder and use of illicit drugs

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:	Pending
Start date (anticipated):	15-09-2008
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

ID: 23010
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL24257.018.08
OMON	NL-OMON23010