Dopamine synthesis capacity in patients with borderline personality disorder and auditory verbal hallucinations

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What are the differences and similarities of dopamine synthesis capacity between patients with AVH and BPD, those with schizophrenia, and healthy controls?

Ethical review	Approved WMO
Status	Will not start
Health condition type	Disturbances in thinking and perception
Study type	Observational invasive

Summary

ID

NL-OMON55346

Source
ToetsingOnline

Brief title
DOPA PET in BPD with AVH

Condition

- Disturbances in thinking and perception

Synonym
auditory verbale hallucinations, hearing voices

Research involving
Human

Sponsors and support

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

Intervention

Keyword: dopamine, hallucination, personality disorder, positron emission tomography

Outcome measures

Primary outcome

Dopamine synthesis capacity as determined by F-DOPA PET

Secondary outcome

• Positive And Negative Syndrome Scale (Kay et al., 1988)

• Questionnaire for Psychotic Experiences (Rosell et al., 2019)

• Dissociative Experiences Scale (Bernstein & Putnam, 1986)

• Jeugd Trauma Vragenlijst (Bernstein et al., 1997)

• Schizotypal Personality Questionnaire (Raine, 1991)

• Outcome Questionnaire 45 (Boswell et al., 2013)

• Cognitive Biases Questionnaire for psychosis (Peters et al., 2014)

• Glutamate and glutamine concentrations

• PRAAT language test

• Shadowing task

Study description

Background summary

Auditory verbal hallucinations (AVH) in patients with borderline personality disorder (BPD) share many similarities with those in patients with schizophrenia. Patients with schizophrenia have increased striatal dopamine synthesis capacity. If patients with BPD and AVH show a similar increase in dopamine synthesis capacity to patients with schizophrenia, then these AVH are likely to be related to, and possibly the result of, dopaminergic dysfunction. In that case, patients with BPD and AVH will benefit from treatment with

antipsychotics.

Study objective

What are the differences and similarities of dopamine synthesis capacity between patients with AVH and BPD, those with schizophrenia, and healthy controls?

Study design

Multicenter cross-sectional observational study

Study burden and risks

The most common risks in previous human PET studies include injection site reactions, musculoskeletal pain, nausea and fatigue. Back pain, anxiety/claustrophobia, insomnia, hypertension, and neck pain were also reported. Because these events could be related in part to the PET scan apparatus and procedures, careful attention should be taken to make the participant aware of the planned procedures and to maximize participants comfort in the scanner. No risks are associated with the procudure for the MRI-scan except for feelings of claustrophobia. Therefore, participants will be informed about the procedure extensively.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

BPD patients
Patients can participate within the BPD group if they fulfil the following criteria: 1. BPD with the aid of the Structured Clinical Interview for DSM-5 Personality Disorders, 2. Age 18 to 60 years, 3. Persistent AVH in a frequency of at least weekly for a duration of 6 months, 4. Female patients are not pregnant. 5. Patients did not participate in a scientific research study during the last six months involving radiation (or any other form of exposure to the same amount of radiation within the past year via e.g., transatlantic flights), 6. Have no magnetic resonance imaging (MRI)-incompatible implants in the body (such as an insulin-pump, pace-maker, or non-removable piercings). 7. Have no metal particles in their eyes. 8. Have no tattoo*s containing red pigments which could form a safety risk during the MRI-scan, 9. No schizophrenia or schizoaffective disorder 10. No use of methylphenidate or dexamphetamine, haloperidol or valproic acid, carbidopa, glucagon and reserpine, 11. Being able to answer questions, 12. No claustrophobia, 13. Mentally competent.
If the diagnoses have been made longer than 4 years prior to inclusion, the SCID 5 and MINI Plus will be used again to confirm the criteria for inclusion.

Schizophrenia group:
Patients can participate within the schizophrenia group if they fulfil the following criteria: 1. Schizophrenia or schizoaffective disorder, diagnosed with the Mini International Neuropsychiatric Interview Plus, 2. Age 18 to 60 years, 3. Persistent AVH in a frequency of at least weekly for a duration of 6 months, 4. Female patients are not pregnant. 5. Patient did not participate in a scientific research study during the past year involving radiation (or any other form of exposure to the same amount of radiation within the last six months via e.g., transatlantic flights), 6. Have no MRI-incompatible implants in the body (such as an insulin-pump, pace-maker, or non-removable piercings). 7. Have no metal particles in their eyes. 8. Have no tattoo*s containing red pigments which could form a safety risk during the MRI-scan, 9. No BPD, and 10. No use of methylphenidate or dexamphetamine, haloperidol or valproic acid, carbidopa, glucagon and reserpine, 11. Being able to answer questions 12. No

claustrophobia, 13. Mentally competent.
Patients do not need to be antipsychotic free as antipsychotics do not affect dopamine synthesis (Jauhar et al., 2019).

Healthy controls
Participants were included in the group of healthy controls if they fulfil the following criteria: 1. No DSM 5 diagnosis of current or past psychiatric disorder or substance dependence other than nicotine dependence, investigated with the SCID-5-PD and MINI Plus, 2. Age 18 to 60 years, 3. No AVH in the last year prior to this study, 4. Female patients are not pregnant. 5. Patient did not participate in a scientific research study during the last six months involving radiation (or any other form of exposure to the same amount of radiation within the past year via e.g., transatlantic flights), 6. Have no MRI-incompatible implants in the body (such as an insulin-pump, pace-maker, or non-removable piercings). 7. Have no metal particles in their eyes. 8. Have no tattoo*s containing red pigments which could form a safety risk during the MRI-scan and 9. No psychiatric pharmacotherapy, 10. No claustrophobia, 11. No use of methylphenidate or dexamphetamine, haloperidol or valproic acid, carbidopa, glucagon and reserpine, 12. Being able to answer questions, 13. Mentally competent.

Exclusion criteria

see inclusion criteria

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: Will not start

Enrollment:	63
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	F-18 FDOPA
Generic name:	6-[18F]-Fluorololevodopa
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	21-12-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-11-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2020-003985-38-NL

Register	ID
CCMO	NL73268.042.20