Determinants of successful discontinuation of antipsychotics used for behavioural symptoms in people with intellectual disability

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To investigate whether the occurrence and severity of neurological withdrawal symptoms during a discontinuation trajectory of antipsychotics used for challenging behaviours in people with intellectual disability is associated with achievement of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mental impairment disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40740

Source
ToetsingOnline

Brief title
DISCAP2

Condition

- Mental impairment disorders
- Psychiatric and behavioural symptoms NEC

Synonym
challenging behaviour

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Subsidie van het Fonds Zorgondersteuning

Intervention

Keyword: Antipsychotics, Challenging behaviour, Discontinuation, Intellectual disability

Outcome measures

Primary outcome

Behavioral parameters are scores of the five subscales of the Aberrant Behavior Checklist (ABC) i.e., irritability, hyperactivity, lethargy, stereotypic behavior and inappropriate speech, and of the Clinical Global Impression scale Improvement (CGI-I).

Secondary outcome

Neurological parameters are scores of extrapyramidal symptoms as measured item 1 through 9 of the Abnormal Involuntary Movement Scale (AIMS), the Barnes akathisia objective symptoms, subjective symptoms and burden scale scale, and items 20, 21, 22, and 31 of the Unified Parkinson Scale (UPDRS). Autonomic symptoms will be measured by the Scale for Outcomes in Parkinson*s disease-Autonomic Symptoms (SCOPA-AUT).

To assess characteristics of caregivers we will use translated and validated versions of the Challenging Behavior Self Efficacy Scale and the Emotional reactions to challenging behavior scale . As far as we know there are no instruments to measure knowledge and cognitions concerning physical, psychological and behavioral effects of psychotropic drug use in caregivers of

individuals with intellectual disability. Therefore we will use a self-designed questionnaire.

We will use the RAND-36 to assess health related quality of life and the subscales *emotional-wellbeing* and *physical-wellbeing* of the quality of life (QUOL) related personal outcomes scale (POS), which has been developed for use in people with intellectual disabilities.

Study description

Background summary

People with intellectual disability (ID) frequently use long-term antipsychotic drugs for challenging behaviours, although the efficacy in this indication has not been proven. Moreover, antipsychotics may cause harmful side effects, which may negatively influence quality of life. Especially neurological side-effects may be serious and sometimes life threatening or irreversible. In order to prevent iatrogenic damage caused by unnecessary antipsychotic drug use discontinuation should be considered.
In daily practice successful discontinuation of antipsychotics may be hampered by neurological withdrawal symptoms, which may remain clinically undiagnosed. Withdrawal symptoms may cause distress and an increase in behavioural symptoms, thus likely leading to higher dosage and ongoing use of the antipsychotic drug. Also, staff- related factors like knowledge and cognitions of psychotropic drug use and attitudes towards challenging behaviours of their clients may influence a successful discontinuation trajectory.

Study objective

To investigate whether the occurrence and severity of neurological withdrawal symptoms during a discontinuation trajectory of antipsychotics used for challenging behaviours in people with intellectual disability is associated with achievement of complete discontinuation.

To study staff-related factors which may be associated with achievement of complete discontinuation of antipsychotics used for challenging behaviours in people with intellectual disability.

To study the effect of discontinuation of antipsychotics used for challenging behaviours on health related quality of life in people with intellectual disability.

To study whether there is an association of severity of neurological side effects of antipsychotics used for challenging behaviours with health related quality of life in people with intellectual disability.

Study design

We will prospectively investigate factors that may be associated with successful discontinuation of long-term used antipsychotics for challenging behaviors as part of clinical practice of intellectual disability physicians or general practitioners. Study settings are living facilities of care providing organizations.

Intervention

Treatment of subjects:
Subjects will taper off long-term used antipsychotic drugs, prescribed on an off-label base by lowering the dose every two weeks with 12.5% of the original dose.

Study burden and risks

The risk associated with participation in this study are negligible, due to the set of safety precautions, while the burden is minimal. It is obvious that study of medication discontinuation in patients with intellectual disability can only be performed in intellectually disabled participants.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Any sex or ethnicity
Age >= 6 years
Functioning below an IQ level of 70 as assessed by an authorized behavioral scientist
Subjects have used one or more antipsychotics for more than one year for challenging behavior
Subjects have been presented a treatment proposal of an attempt to discontinue antipsychotics by their physician.

Exclusion criteria

A history of schizophrenia, a bipolar disorder, or affective psychosis according to DSM IV or ICD-10 criteria
A history of unsuccessful withdrawal of antipsychotics in the past 6 months

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2015
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	03-11-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-11-2014
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
Other	EudraCT 2014-002686-30

Register	ID
CCMO	NL50403.042.14