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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21589

Source
NTR

Brief title
AFBAP2

Health condition

off-label use; antipsychotics;long-term use; behavioural symptoms; challenging behaviours; problem behaviours, intellectual disability; staff-related factors; attitudes; cognitions;knowledge; neurological withdrawal symptoms; extrapyramidal symptoms; autonomic symptoms; quality of life

Sponsors and support

Primary sponsor: University Medical Centre Groningen/department psychiatry
Source(s) of monetary or material Support: Stichting Zorgondersteuningsfonds the Netherlands

Intervention

Outcome measures

Primary outcome

Achievement of complete discontinuation at the time point of 16 weeks (two weeks after the study discontinuation schedule)

Secondary outcome

Achievement of complete discontinuation at the time points of 28 weeks and 40 weeks.

Behaviour:

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

Neurological symptoms:

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).

Characteristics of caregivers:

Translated and validated versions of the Challenging Behavior Self Efficacy Scale and the Emotional reactions to challenging behavior scale

Quality of life:
RAND 36
The subscales “emotional-wellbeing” and “physical-wellbeing” of the quality of life (QUOL) related personal outcomes scale (POS),

Study description

Background summary

Rationale: People with intellectual disability (ID) frequently use long-term antipsychotic drugs for challenging behaviors, 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.
Objectives: To investigate whether the occurrence and severity of neurological withdrawal symptoms during the discontinuation trajectory is associated with achievement of complete discontinuation. To investigate staff-related factors which may be associated with successful discontinuation of antipsychotics used for challenging behaviours in people with ID.
Secondary objectives: To study the effect of discontinuation on health related quality of life. To study whether there is an association of severity of neurological side effects with health related quality of life
Study design: Prospective study
Study population: People with intellectual disability aged six years and over, who use antipsychotic drugs for challenging behaviours for more than one year and who are presented a treatment proposal of an attempt to scheduled discontinuation by their physicians, as part of their regular treatment.

Intervention: A series of eight brief medical exams during the discontinuation trajectory, in which antipsychotics will be tapered off by lowering the dose every 2 weeks with 12.5% of baseline dosage.
Main study parameters: Study parameters are scores of extrapyramidal symptoms, scores of behavioral measurements, scores of questionnaires of staff-related factors and scores of questionnaires of health related quality of life.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The proposed treatment is part of regular medical practice. Also, the medical

assessments of physical symptoms are part of regular medical medication controls whereby 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.

Study objective

Succesful discontinuation of antipsychotics used for behavioural symptoms in people with intellectual disability is determined by staff-related factors and by neurological withdrawal symptoms.

Study design

Data collection will take place at baseline and at 4, 8, 12, and 16 weeks after the first dose reduction. Follow-up data collection is at 6, 12, and 26 weeks after the scheduled time point of complete discontinuation.

Intervention

discontinuation of long-term used antipsychotics for behavioural symptoms whereby dosereduction will take place every two weeks with appr. 12.5 % of baseline dosage in a time schedule of 14 weeks

Contacts

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Eligibility criteria

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.

Written informed consent of the legal representative.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• 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

• Use of risperidone

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

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

Ethics review

Positive opinion

Date:	04-11-2015
Application type:	First submission

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
NTR-new	NL5394
NTR-old	NTR5519
Other	2014-002686-30 : Eudra CT

Study results