Long-term use of antipsychotics for behavioral symptoms in patients with mental retardation; a controlled discontinuation study.

No registrations found.

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

Summary

ID

NL-OMON22173

Source
Nationaal Trial Register

Brief title
DISCAP

Health condition

mental retardation; antipsychotics; discontinuation; behavioral symptoms

Sponsors and support

Primary sponsor: Gerda de Kuijper
Source(s) of monetary or material Support: Vanboeijen

Intervention

Outcome measures

Primary outcome

Aberrant Behavior Checklist.

Secondary outcome

1. Weight;

2. middle-circumference;

3. glucose metabolism;

4. lipid metabolism;

5. bone metabolism;

6. autonomic symptoms;

7. signs of tardive dyskinesia and tardive akathisia.

Study description

Background summary

Background of the study:

A substantial proportion of individuals with mental retardation chronically utilizes antipsychotic medication. This may only be partially explained by the presence of psychiatric disorders. Often, antipsychotics are being prescribed without a clear indication, for ameliorating behavioral symptoms, such as aggression, and irritable and provocative behavior.

Long time use of antipsychotics may have substantial health risks, including weight gain, glucose dysregulation, hyperlipidemia, and hyperprolactinemia. Another side-effect associated with the long term use of antipsychotics is osteoporosis, resulting from hyperprolactinemia-induced hypogonadism. Other significant side-effects may also occur in association with the use of antipsychotics, such as emotional and cognitive blunting, and extrapiramidal symptoms like dystonia, dyskinesia, and akathisia.

Objective of the study:

The primary objective of this study is to test the hypothesis that discontinuation of antipsychotics does not lead to deterioration in functioning as measured by the ABC.

Study design:

A randomized controlled discontinuation study design will be used.

Study population:

Subjects will be recruited from institutions for intellectually disabled persons in the North and Middle of the Netherlands. All residents aged between 15-65 year currently receiving antipsychotics for behavioral symptoms for 6 months or longer are eligible. Exclusion criteria include a) a history of schizophrenia, affective psychosis or a bipolar disorder according to DSM IV criteria and b) a history of unsuccessful withdrawal of antipsychotics in the past 6 months.

Intervention:

A random number table will allocate 100 subjects in a 1:1 ratio to either a group that will be gradually tapered off antipsychotic treatment over 14 weeks or a group that will be tapered off over 28 weeks.

Primary study parameters/outcome of the study:

The primary outcome measure will be the proportion of people developing marked behavioral symptoms calling for prescription of (higher doses of) antipsychotics and thus leading to study withdrawal in both treatment groups.

Secundary study parameters/outcome of the study:

Weight, middle circumference, BMI, fasting glucose, fasting triglyceride, total cholesterol, HDL-and LDL-cholesterol, prolactin, CTX, P1NP, the Clinical Global Impression (CGI), and the Visual Analogue Scale (VAS). Extrapyramidal symptoms (AIMS), autonomic dysfunction (SCOPA-AUT).

Study objective

Discontinuation of long term use of antipsychotics for behavioral symptoms in patients with mental retardation does not lead to deterioration in mental functioning.

Study design

Baseline data will be collected prior to the discontinuation (visit 0). Throughout the discontinuation phase, participants will be controlled every 2 or 4 weeks (visits 1 through 8). Twelve weeks after full discontinuation one additional visit will take place for both study groups. In total 10 visits will take place for both groups.

Intervention

Discontinue antipsychotic treatment in a period of 14 weeks or in 28 weeks. Dose reduction will take place every two or four weeks by lowering the dose with 12.5% of the original.

Contacts

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Eligibility criteria

Inclusion criteria

1. Intellectually disabled persons (i.e., functioning at an IQ below 70);

2. aged between 15-65 year;

3. living in residential facilities, who currently receive the antipsychotic agents risperidone, pipamperone, haloperidol, pimozide, levomepromazine, and/or olanzapine for behavioral symptoms for 12 months or longer.

Exclusion criteria

1. A history of schizophrenia, a bipolar disorder, or affective psychosis according to DSM IV criteria;

2. a history of unsuccessful withdrawal of antipsychotics in the past 6 months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2009
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	17-12-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 32602
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1524
NTR-old	NTR1595
CCMO	NL24349.042.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON32602

Study results

Summary results
Use of antipsychotic drugs in individuals with intellectual disability: prevalence and reasons for prescription. (Gerda de Kuijper, Pieter J Hoekstra, Frank Visser, Frans Scholte†, Corine Penning, Heleen Evenhuis
Journal of Intellectual Disability Research 2010;54:659-67).

Effects of controlled discontinuation of long-term used antipsychotics for behavioural symptoms in individuals with intellectual disability. (Gerda de Kuijper, Heleen Evenhuis, Ruud Minderaa, Pieter J. Hoekstra
Journal of Intellectual Disability Research , accepted for publication, 2012, Epub).

Determinants of physical health parameters in individuals with intellectual disability who use long-term antipsychotics. (Gerda de Kuijper, Hans Mulder, Heleen Evenhuis, Frans Scholte †, Frank Visser, Pieter J. Hoekstra
Research in Developmental Disabilities, accepted for publication, 2013).

Effects of controlled discontinuation of long-term used antipsychotics on weight and metabolic parameters in individuals with intellectual disability. (Gerda de Kuijper, Hans Mulder, Heleen Evenhuis, Frank Scholte †, Frank Visser, Pieter J. Hoekstra
Journal of Clinical Psychopharmacoloy, august 2013).

Effects of controlled discontinuation of long-term used antipsychotics on prolactin and bone turnover markers in patients with intellectual disability. (Gerda de Kuijper, Hans Mulder, Frans Scholte †, Frank Visser, Heleen Evenhuis, Pieter J. Hoekstra
Journal of Clinical Psychopharmacoloy, accepted for publication, 2013).