

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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22173

Bron

Nationaal Trial Register

Verkorte titel

DISCAP

Aandoening

mental retardation; antipsychotics; discontinuation; behavioral symptoms

Ondersteuning

Primaire sponsor: Gerda de Kuijper

Overige ondersteuning: Vanboeijen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

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 extrapyramidal 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.

Secondary 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).

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	17-12-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 32602
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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 Psychopharmacology, 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 Psychopharmacology, accepted for publication, 2013).