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

Published: 08-10-2008
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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Personality disorders and disturbances in behaviour
Study type	Interventional

Summary

ID

NL-OMON32602

Source
ToetsingOnline

Brief title
DISCAP

Condition

- Personality disorders and disturbances in behaviour

Synonym
mental retardation; intellectual disability

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Bijdrage van de deelnemende instellingen;

Open Anck en Steunfonds 's Heeren Loo

Intervention

Keyword: antipsychotics, behavioral symptoms, discontinuation, mental retardation

Outcome measures

Primary outcome

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 outcome

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 description

Background summary

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.

Study objective

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.

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

Study burden and risks

Participants will undergo two venapunction and three physical examinations including measurements of weight and middle circumference, pulse and blood pressure, and examination for extrapyramidal symptoms. As a result of antipsychotics discontinuation there may be a risk of (temporarily) worsening of behavior.

Contacts

Public
Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Institutionalized persons with mental retardation aged between 15-65 year currently receiving antipsychotics for behavioral symptoms for 12 months or longer are eligible. Behavioral symptoms will be defined as challenging, disruptive, or aggressive behavior to self, others, or materials, either physically or verbally, including sexually aggressive behavior.

Exclusion criteria

a) a history of schizophrenia, a bipolar disorder, or affective psychosis according to DSM IV criteria and b) a history of unsuccessful withdrawal of antipsychotics in the past 6 months.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2019
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dipiperon
Generic name:	pipamperone
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Haldol
Generic name:	haloperidol
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Nozinan
Generic name:	levomepromazine
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Orap
Generic name:	pimozide
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Risperdal
Generic name:	risperidone
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	08-10-2008
Application type:	First submission

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

ID: 22173
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2007-005451-42-NL
CCMO	NL24349.042.08
OMON	NL-OMON22173