Off-label use of risperidone in people with intellectual disability: A discontinuation study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27969

Source
Nationaal Trial Register

Brief title
RISPID

Health condition

challenging behavior
intellectual disability
off-label risperidone
off-label antipsychotics

Sponsors and support

Primary sponsor: University Medical Center Groningen (UMCG)
Source(s) of monetary or material Support: Stichting Fonds Zorgondersteuning and ZonMw

Intervention

Outcome measures

Primary outcome

Behavior measured by the irritability subscale of the Aberrant Behavior Checklist (ABC)

Secondary outcome

- Other ABC subscales

- Clinical Global Impression Scale (CGI)

- Abnormal Involuntary Movement Scale (AIMS)

- Barnes Akathisia Rating Scale (BARS)

- Unified Parkinsons Disease Rating Scale (UPDRS)

- Scales for Outcomes in Parkinson's disease AUTonomic symptoms (SCOPA-AUT)

- Epworth Sleepiness Scale (ESS)

- Personal Outcome Scale (POS)

- RAND-36

- Physical measures: length, weight, waist circumference, heart rate and blood pressure

- blood counts

From a blood draw, we will obtain measures on:

- metabolism: Fasting glucose, insulin, tryglycerides, high-density lipoproteins (HDL), low-density lipoproteins (LDL), leptine, total cholestrol and HbA1C

- endocrine parameters: prolactin, testosterone
- bone turnover: P1NP, CTx, osteocalcine, vitamin D and calcium

- thyroid function: TSH, T4 and parathyroid hormone (PTH)

- pharmacokinetics: risperidone and 9-hydroxyrisperidone concentrations

- albumine, creatine, potasium and sodium levels
predictor variables:

- demographic data and socio-economic status

- treatment history and psychiatric diagnosis

- Tanner stages of pubertal development

- challenging behavior self-efficacy scale

- the emotional reactions to challenging behavior scale

- knowledge of psychotropic drugs

- beliefs, support of caregivers

Study description

Background summary

Often people with intellectual disability use antipsychotics, including risperidone, for the treatment of challenging behavior. This use of risperidone is off-label, often long-term and can cause many side-effects. For that reason we will test the effectiveness of risperidone after long-term use in challenging behavior. This study is a placebo-controlled discontinuation study of risperidone, in which the effect of discontinuation is tested on behavior, health and quality of life.

Study objective

We expect that it is possible to discontinue long-term (>1 year) used risperidone prescribed for challenging behaviors in people with intellectual disability without a clinical relevant change in behavior. Furthermore, as a result of discontinuation we expect that health outcomes will improve, such as weight, cholesterol levels, prolactin levels and neurological symptoms (extrapyramidal symptoms and autonomic symptoms). As a result we also expect quality of life to improve after discontinuation of risperidone.

Study design

week 0: baseline measurements

week 2: start discontinuation

week 6, 10, 14: measurements during discontinuation

week 16: end of discontinuation

week 18 and 24: blinded follow-up measurements

week 24: end of blinded phase

week 42: naturalistic follow-up

Intervention

the intervention group will gradually discontinue the use of risperidone to placebo. The control group will continue the use of risperidone on their normal dose

Contacts

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Eligibility criteria

Inclusion criteria

1. IQ<70 as assessed by an authorized behavioral therapist

2. Age > 6 years

3. No history of chronic psychosis

4. Risperidone use>1 year

5. Challenging behavior was the reason of prescription of risperidone

6. Informed consent obtained from legal representative

Exclusion criteria

1. A history of schizophrenia, a bipolar disorder, or affective psychosis according to DSM IV or ICD-10 criteria

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

3. The use of other antipsychotics in addition to risperidone use

4. Risperidone is administered as long-acting injections

5. Clients who do not receive 24 hour/a day care (by either a service provider or parents/family)

6. Clients who are pregnant or have the intention to become pregnant

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2015
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion
Date: 28-10-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43644
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5252
NTR-old	NTR5509
CCMO	NL53217.042.15
OMON	NL-OMON43644

Study results