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

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27969

Bron
Nationaal Trial Register

Verkorte titel
RISPID

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)
Overige ondersteuning: Stichting Fonds Zorgondersteuning and ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2015
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-10-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43644
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten