Withdrawing off-label antipsychotics in people with intellectual disabilities: why does it fail?

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Failure of discontinuation of off-label antipsychotics in people with intellectual disabilities is the result of (1) subjective interpretation of behavior by caregivers, influenced by fear of worsening of behavior after drug reduction, (2) a…

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

Samenvatting

ID

NL-OMON21687

Bron
NTR

Verkorte titel
N/A

Aandoening

Antipsychotics, intellectual disabilities
Antipsychotica, verstandelijke beperking

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: The Netherlands Organisation for Health Research and Development (ZonMW)
Health Aging and ID consort

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The percentage of participants completing the protocol in the “discontinuation group” (gradual decline of AP dose) compared to the “control group” (continuing AP dose).

Toelichting onderzoek

Achtergrond van het onderzoek

Antipsychotics are often used off-label in people with intellectual disabilities for challenging behavior (20-45% of the population receiving formal healthcare). There is no evidence for efficacy. However, metabolic and extrapyramidal side effects are very common. Despite dubious efficacy and concerns about safety, full withdrawal cannot be achieved in over 50% of patients (even if behavior does not deteriorate). We postulate 3 mechanisms: (1)effects of subjective interpretation of behavior by caregivers, influenced by fear of worsening behaviour after drug reduction, (2)it cannot be excluded that some patients might benefit from AP treatment, through a direct effect on behavior, improvement of sleep, or because of previously undiagnosed psychiatric illness, (3)withdrawal symptoms may occur, such as agitation, mania, akathisia, and withdrawal dyskinesia. These symptoms may be misinterpreted as recurrence of challenging behaviour. These hypotheses are tested in a double-blinded placebo-controlled study: participants will be divided in a discontinuation group (gradual decline of AP) and a control group (continuing AP dose). Behaviour, sleep, psychiatric disorders and side effects will be measured and compared between groups. If no differences between groups are found regarding changes in behaviour or drop out of study, the first hypothesis will be supported. Study findings will be included in new guidelines replacing current practice-based off-label prescription of AP.

Doel van het onderzoek

Failure of discontinuation of off-label antipsychotics in people with intellectual disabilities is the result of (1) subjective interpretation of behavior by caregivers, influenced by fear of worsening of behavior after drug reduction, (2) a beneficial effect of AP treatment, through a direct effect on behavior, improvement of sleep, or because of previously undiagnosed psychiatric illness, (3)withdrawal symptoms, such as agitation, mania, akathisia, and withdrawal dyskinesia are misinterpreted as recurrence of behavioral problems.

Onderzoeksopzet

Dose reduction will start 2 weeks after inclusion. The code will be broken after 22 weeks, patients will be followed open label for 18 weeks (care as usual). The total study duration is 40 weeks. Assessments will be performed at baseline, and 2,4,5,6,8,10,12,16,22,40 weeks

after start.

Onderzoeksproduct en/of interventie

Risperidone or pipamperone
tablets will be replaced by liquid form. All participants receive a dosage scheme:
-25% of the original dosage every 4 weeks in the discontinuation group, dosage remains unaltered in the control group.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adults with ID (IQ < 70), using off-label antipsychotics (pipamperone or risperidone) since > 1 year for behavioral problems.

Participants are living (=>ZZP4) in three participating ID care organizations of the HA-ID consort.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Diagnosis of psychosis, dementia, schizophrenia, psychotic disorder NOS, delirium, failed attempt to withdraw AP < 6 months ago, usage of >1 AP drug

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2019
Aantal proefpersonen:	122
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	25-05-2018

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7027
NTR-old	NTR7232
Ander register	METC Erasmus MC Rotterdam : MEC 2016-573

Resultaten

Samenvatting resultaten
1. Beumer S, Festen, D. Reduction or discontinuation of antipsychotics for challenging behavior in adults with intellectual disability: why does it fail?” Lancet Psychiatry. Vol 4, No3 e2,March 2017