Methylfenidaat afbouw studie bij kinderen

No registrations found.

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

Summary

ID

NL-OMON27718

Source
Nationaal Trial Register

Brief title
Methylfenidaat Afbouw Studie bij Kinderen (MASK)

Health condition

ADHD; attention deficit/hyperactivity disorder; methylphenidate; long-term effectiveness; methylfenidaat; lange termijn effectiviteit; aandachtstekortstoornis met hyperactiviteit

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

ADHD-DSM-5 RS

Secondary outcome

Rating scales

• Clinical Global Impression Scale of Improvement (CGI-I).

• Criteria of Oppositional Defiant Disorder (ODD)

• Side en withdrawal effects based on adapted version of the Barkley Side Effect Rating scale (BSERS).

• Sleep Disturbances Scale for Children (SDSC)

• Appetite of the child

• Retrospective Overt Aggression Scale (R-MOAS)

• Kindl-R

• Parental Stress Scale (PSS)

• Family atmosphere questions

• Parental Frustrations Questionnaire (PFQ)

• Child Depression Inventory (CDI)

• Strength and Difficulties Questionnaire (SDQ).

• Conners Teacher Rating Scale-Revised: short form (CTRS-R:S).

physical measures

• weight

• height

• Blood pressure

• Pulse

Biomarkers

• Blood draw (ferritin, zinc)

Neuropsychological tests

• Amsterdam Neuropsychological Tasks (three subtests)

Mediators/predictors

• treatment history, history and compliance.

Child factors

• sex, age, ethnicity and school type

• estimation of IQ

• Psychiatric diagnoses

• Tanner stage + some questions of Physical Development Scale (PDS)

• Temperament (Behavioural Avoidance and Inhibition Scale [BISBAS], Inventory of Callous and Unemotional traits [ICU], Brief Sensation Seeking Scale [BSSS])

• DNA (blood draw)

• Cortisol from hair

• Stressful events

Parental factors

• Socio-economic status

• Egna Minnen Beträffende Uppfostran (EMBU)

• Adult ADHD Rating scale (AARS)

• Parenting Sense of Competence Scale (PSOC)

• Maudsley Marital Questionnaire (MMQ)(subschale Marital adjustment)

Study description

Study objective

We will test the hypothesis that ongoing use of methylphenidate is superior to placebo with regard to ADHD symptom severity in children and adolescents who have used methylphenidate for two years or longer.

Study design

baseline

after four weeks

after seven weeks

Blind will be broken

fully natural follow up after six months

Intervention

The participating subjects will be randomized (ratio 1:1) to either continued use of methylphenidate or to placebo during seven weeks. Withdrawal will be gradually over a period of three weeks, followed by four weeks of complete placebo. There will be three visits, at baseline, after four weeks and after seven weeks. After six months there will be a follow up by telephone.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Children between the ages of eight to eighteen, any ethnicity or cultural background.

• Children with their first prescription of any form of methylphenidate at least two years ago.

• Children who are for at least the last four weeks the subject has been using methylphenidate in the form of Concerta 36 mg or 54 mg.

• Children with an IQ > 70 (based on a previous IQ test or attending regular education).

• Parents (or the legal guardian) and children (≥ twelve years) have provided informed consent to participate in the study.

Exclusion criteria

Excluded from participation in this study will be:

• Children who have not been using of methylphenidate for a continuous period > 2 months during the last two years.

• Children of parents who are planning to start new psychosocial or pharmacological therapies during the blinded period.

• Children and or parents who are unable to understand or comply with the protocol.

• Children who have any other significant disease or disorder which, in the opinion of the investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant’s ability to participate in the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Control: Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-06-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41851
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5120
NTR-old	NTR5252
CCMO	NL49436.042.14
OMON	NL-OMON41851

Study results