Methylfenidaat afbouw studie bij kinderen

Gepubliceerd: 16-06-2015 Laatst bijgewerkt: 15-05-2024

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.

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

Samenvatting

ID

NL-OMON27718

Bron
Nationaal Trial Register

Verkorte titel
Methylfenidaat Afbouw Studie bij Kinderen (MASK)

Aandoening

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

Ondersteuning

Primaire sponsor: Universitair Medisch Centrum Groningen
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

ADHD-DSM-5 RS

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

baseline

after four weeks

after seven weeks

Blind will be broken

fully natural follow up after six months

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Universitair Medisch Centrum Groningen - Huispostcode XA10

A.F.M. Matthijssen
Postbus 30.001

Groningen 9700 RB
The Netherlands
Tel: 050-361 55 89

Wetenschappelijk

Universitair Medisch Centrum Groningen - Huispostcode XA10

A.F.M. Matthijssen
Postbus 30.001

Groningen 9700 RB
The Netherlands
Tel: 050-361 55 89

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Controle: Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2015
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-06-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41851
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten