Looking into the eye of ADHD.

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An intervention with Methylphenidate, Melatonin or Light Therapy will lead to changes in visual functioning.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22441

Bron
Nationaal Trial Register

Verkorte titel
EyeADHD

Aandoening

Attention-deficit/hyperactivity disorder (ADHD); Sleep; Circadian disturbances; Eye functioning

Ondersteuning

Primaire sponsor: PsyQ Haaglanden
Kenniscentrum ADHD bij volwassenen
Overige ondersteuning: ZonMw ; PsyQ Expertise Center Adult ADHD

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The change in Post-Illumination Pupil Response (PIPR).

Toelichting onderzoek

Achtergrond van het onderzoek

The study design consists of three phases, (1) exploring eye functioning in ADHD and healthy controls, (2) an explorative single-dose intervention of treatments commonly used in adults with ADHD on eye functioning, and (3) an effect evaluation of a 3-week treatment period of these commonly used treatments on eye functioning. This trial registration number only incorporates phase 3 of the project.

In Phase 3, ADHD patients that have participated in Phase 1 will be randomized for any of the interventions or for a placebo condition (as a control condition for Mph and Mel) or for a waiting list group (as a control condition for LT). Participants that have already participated in Phase 2, with major substance abuse, or any contra-indication for the interventions will be excluded. Each group will have n=10 participants per group, or, if the Phase 2 results indicate so, larger groups will be determined. All conditions and medication intake schedules are designed according usual treatment regimes:

1A) Mph, 3 x 20 mg/day at 8 AM, 12 PM and 4 PM during 3 weeks, n=10

1B) Placebo, 3 x 20mg/day at 8 AM, 12 PM and 4 PM during 3 weeks, n=10

2A) LT, 30 minutes/day in the morning during 3 weeks, n=10

2B) Waiting list during 3 weeks, n=10

3A) Mel, 3 mg/day in the evening 1 h before desired bedtime during 3 weeks, n=10

3B) Placebo, 3 mg/day in the evening 1 h before desired bedtime during 3 weeks, n=10

At baseline and ffter the 3-week intervention period, an eye functioning assessment battery will be assessed. The intra-individual change of the outcomes between the baseline and the Phase 3 measurements will be compared between the Mph and the placebo group, between the LT and waiting list group, and between the Mel and Placebo group. The correlation between the PIPR or any other eye functioning measure and the effect of the intervention on ADHD symptoms or circadian rhythm will be investigated. Any comorbidity, self-reported oversensitivity to light, and minor substance abuse will be analyzed as covariates in regression models when evaluating the effect of the interventions on the eye functioning improvement.

Doel van het onderzoek

An intervention with Methylphenidate, Melatonin or Light Therapy will lead to changes in visual functioning.

Onderzoeksopzet

The assessments will take place at baseline and immediately after the 3-week intervention period.

Onderzoeksproduct en/of interventie

A 3-week intervention of one of the following:

1A) Methylphenidate, 3 x 20 mg/day

1B) Placebo, 3 x 20mg/day

2A) Light Therapy, 30 minutes/day

2B) Waiting list

3A) Mel, 3 mg/day

3B) Placebo, 3 mg/day

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patient group and control group: Age 18 to 40 years old. Patient group: Diagnosis of ADHD.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patient group and control group: Severe psychiatric comorbidity; substance abuse; contraindication for the intervention. Control group: ADHD; use of stimulant medication.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2015

Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL4187
NTR-old	NTR4337
Ander register	UTN: U1111-1151-6270 : 2013-005017-12
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A