Looking into the eye of ADHD.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22441

Source
NTR

Brief title
EyeADHD

Health condition

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

Sponsors and support

Primary sponsor: PsyQ Haaglanden
Kenniscentrum ADHD bij volwassenen
Source(s) of monetary or material Support: ZonMw ; PsyQ Expertise Center Adult ADHD

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- A change in refractive error test for myopia (nearsightedness), hyperopia (farsightedness),

astigmatism (cylindrical error), presbyopia (focus difficulty), and strabismus (alignedness of the eyes);

- A change in colour discrimination ability;

- A change in oculomotor functioning;

- A change in perimetry score (visual field);

- A change in the self-reported oversensitivity to light.

- A change in the self-reported ADHD symptoms on the ADHD Rating Scale (ADHD-RS);

- A change in the performance on the QbTest, which measures ADHD symptoms objectively;

- A change in Dim-Light Melatonin Onset (DLMO);

- A change in chronotype as measured by the Munich Chronotype Questionnaire (MCTQ);

- A change in chronotype as measured by the Morningness-Eveningness Questionnaire (MEQ);

- A change in fatigue as measured by the Multidimensional Assessment of Fatigue (MAF);

- A change on the Seasonal Pattern Assessment Questionnaire (SPAQ).

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

Patient group and control group: Severe psychiatric comorbidity; substance abuse;

contraindication for the intervention. Control group: ADHD; use of stimulant medication.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2015
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4187
NTR-old	NTR4337
Other	UTN: U1111-1151-6270 : 2013-005017-12
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A