

Added Value of the Oculomotor and Cognitive Examination in the Management of Patients with ADHD

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ClinicalTrials.gov Identifier: NCT03411434

Recruitment Status : Recruiting

First Posted : January 26, 2018

Last Update Posted : January 26, 2018

See **Contacts and Locations**

Sponsor:

Centre Hospitalier Rouffach

Information provided by (Responsible Party):

Fabrice Duval, Centre Hospitalier Rouffach

• Study Details

- Tabular View
- No Results Posted

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- How to Read a Study Record

Study Description

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Brief Summary:

ADHD is a neurodevelopmental disorder characterized by symptoms of inattention and / or hyperactivity-impulsivity that affects nearly 6% of school-aged children and persists into adulthood. More and more studies are interested in biomarkers of this pathology. The oculomotricity, which allows to highlight deficits motor and attention present in ADHD, is used routinely in the expert centers. In general, the pharmacological treatment of ADHD is associated with a clinical response in approximately 70% of cases. Today, there is no review to predict the individual response to treatment.

Hypotheses The investigators hypothesize that a precise analysis of the oculomotor markers will allow to measure the improvement of the symptomatology of the ADHD disorder following the introduction of the psycho-stimulatory treatment. In other words, the investigators hypothesize that these markers could be a useful aid in patient follow-up by the clinician and allow early identification of responder and non-responder patients.

Primary objective The main objective of this study is to measure the added value of oculomotor examination in the follow-up of psycho-stimulant-treated ADHD patients.

Main Evaluation Criteria The primary endpoint is oculomotor performance. Parameters analyzed for each saccade are latency, amplitude, duration, average speed, direction.

Secondary Criteria Evaluation (s) Correlations will be established between oculomotor data and scores obtained at the clinical scales assessing ADHD symptoms of inattention and hyperactivity as well as cognitive performance. The data obtained before the introduction of the psycho-stimulant treatment (V0, baseline) will be compared with those obtained after acute administration of methylphenidate (10 mg orally, V1) and during the follow-up visit at 6 months (V2).

Condition or disease	Intervention/
Attention Deficit Hyperactivity Disorder	Drug: Methylphenidate Oral Tablet

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Study Design

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Study Type : Interventional (Clinical Trial)

Estimated Enrollment : 90 participants

Intervention Model: Single Group Assignment

Intervention Model Description: Interventional study designed to evaluate routine care. The patients are their own controls. Oculomotor and neurocognitive performances are assessed at baseline (V0), during the methylphenidate test (V1), and after 6 months of methylphenidate treatment

Masking: None (Open Label)

Primary Purpose: Other

Official Title: Added Value of the Oculomotor and Cognitive Examination in the Management of Patients With Attention Deficit Disorder With or Without Hyperactivity. Interventional Study to Evaluate Current Care

Actual Study Start Date : February 17, 2014

Estimated Primary Completion Date : December 31, 2019

Estimated Study Completion Date : December 31, 2019

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

Drug Information available for: Methylphenidate Methylphenidate hydrochloride

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Experimental: ADHD patients 90 patients will be enrolled and assessed (i.e., neurocognitive and oculomotor tests) at baseline ; after a single low dose of methylphenidate (10 mg orally); and after 6 months of adequate dose of methylphenidate oral tablet	Drug: Methylphenidate Oral Tablet cf arm group description Other Names: <ul style="list-style-type: none">• oculometry (eye tracking)• neurocognition (TAP battery)

Outcome Measures

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Primary Outcome Measures :

1. Change in saccade latency after acute and chronic 6-month administration of methylphenidate vs. baseline [Time Frame: Baseline (V0); methylphenidate test (V1; i.e., two weeks after V0, one hour after

ingestion of a single low dose administration of MPH [10 mg orally given at 8 AM]); after 6 month's treatment with methylphenidate oral tablet (V2)]

Latency (time between the onset of the target and the beginning of the eye movements in milliseconds)

2. Change in saccade average speed after acute and chronic 6-month administration of methylphenidate vs. baseline [Time Frame: Baseline (V0); methylphenidate test (V1; i.e., two weeks after V0, one hour after ingestion of a single low dose administration of MPH [10 mg orally given at 8 AM]); after 6 month's treatment with methylphenidate oral tablet (V2)]

Average speed of the saccade (degree per second)

3. Change in saccade accuracy after acute and chronic 6-month administration of methylphenidate vs. baseline [Time Frame: Baseline (V0); methylphenidate test (V1; i.e., two weeks after V0, one hour after ingestion of a single low dose administration of MPH [10 mg orally given at 8 AM]); after 6 month's treatment with methylphenidate oral tablet (V2)]

Saccade accuracy (characterized by the ratio of the amplitude of the first saccade to the amplitude of the target, expressed in percentage)

4. Change in direction errors after acute and chronic 6-month administration of methylphenidate vs. baseline [Time Frame: Baseline (V0); methylphenidate test (V1; i.e., two weeks after V0, one hour after ingestion of a single low dose administration of MPH [10 mg orally given at 8 AM]); after 6 month's treatment with methylphenidate oral tablet (V2)]

Direction errors (in percentage)

5. Change in anticipatory saccades after acute and chronic 6-month administration of methylphenidate vs. baseline [Time Frame: Baseline (V0); methylphenidate test (V1; i.e., two weeks after V0, one hour after ingestion of a single low dose administration of MPH [10 mg orally given at 8 AM]); after 6 month's treatment with methylphenidate oral tablet (V2)]

Anticipatory saccades (saccade initiated < 80 msec after target appearance, in percentage)

6. Change in express saccades after acute and chronic 6-month administration of methylphenidate vs. baseline [Time Frame: Baseline (V0); methylphenidate test (V1; i.e., two weeks after V0, one hour after ingestion of a single low dose administration of MPH [10 mg orally given at 8 AM]); after 6 month's treatment with methylphenidate oral tablet (V2)]

Express saccades (reaction time between 80 and 130 msec, expressed in percentage).

Secondary Outcome Measures :

1. Associations between clinical outcome after 6 month's methylphenidate treatment and change in oculomotor performance (from V0 to V1, V0 to V2, and V1 to V2) [Time Frame: Baseline (V0);

methylphenidate test (V1; i.e., two weeks after V0, one hour after ingestion of a single low dose administration of MPH [10 mg orally given at 8 AM]); after 6 month's treatment with methylphenidate oral tablet (V2)]

Clinical Global Impression (CGI). The CGI is rated on a 7-point scale, with the severity of illness scale using a range of responses from 1 (normal) through to 7 (amongst the most severely ill patients). Global improvement or change (CGI-C) scores range from 1 (very much improved) through to 7 (very much worse). Treatment response ratings should take account of both therapeutic efficacy and treatment-related adverse events and range from 0 (marked improvement and no side-effects) and 4 (unchanged or worse and side-effects outweigh the therapeutic effects). Each component of the CGI is rated separately; the instrument does not yield a global score.

2. Associations between oculomotor data and neurocognitive test results [Time Frame: Baseline (V0); methylphenidate test (V1; i.e., two weeks after V0, one hour after ingestion of a single low dose administration of MPH [10 mg orally given at 8 AM]); after 6 month's treatment with methylphenidate oral tablet (V2)]

computerized neurocognitive tests (KITAP for children up to 10 years; TAP for children above 11 years, adolescents, and adults)

Eligibility Criteria

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Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).

Ages Eligible for Study: 7 Years to 50 Years (Child, Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- ADHD diagnosis according to DSM-IV-TR criteria
- Beneficiary of a social security scheme
- Having undergone an oculomotor examination as part of their usual care
- Normal neurological examination

Exclusion Criteria:

- Intellectual Disability (IQ < 70)
- Proven neurological pathology or identified genetic syndrome
- Vestibular pathology
- Ear, nose, and throat (ENT) pathology
- Neuro-ophthalmological pathology uncorrected by corrective glass (<10/10 in binocular vision)

Contacts and Locations

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT03411434**

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Recruiting

Sponsors and Collaborators

Centre Hospitalier Rouffach

Investigators

Principal Investigator: Fabrice Duval Centre Hospitalier Rouffach

More Information

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Publications:

Munoz DP, Armstrong IT, Hampton KA, Moore KD. Altered control of visual fixation and saccadic eye movements in attention-deficit hyperactivity disorder. *J Neurophysiol.* 2003 Jul;90(1):503-14. Epub 2003 Apr 2.

Kurscheidt JC, Peiler P, Behnken A, Abel S, Pedersen A, Suslow T, Deckert J. Acute effects of methylphenidate on neuropsychological parameters in adults with ADHD: possible relevance for therapy. *J Neural Transm (Vienna).* 2008;115(2):357-62. doi: 10.1007/s00702-008-0871-4. Epub 2008 Feb 12.

Responsible Party: Fabrice Duval, MD, Psychiatrist, Centre Hospitalier Rouffach

ClinicalTrials.gov Identifier: NCT03411434 History of Changes

Other Study ID Numbers: AO-005/20131104

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Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Fabrice Duval, Centre Hospitalier Rouffach:
oculomotor performances

neurocognition
methylphenidate

Additional relevant MeSH terms:

Attention Deficit Disorder with Hyperactivity
Hyperkinesia
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders
Dyskinesias
Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms

Methylphenidate
Central Nervous System Stimulants
Physiological Effects of Drugs
Dopamine Uptake Inhibitors
Neurotransmitter Uptake Inhibitors
Membrane Transport Modulators
Molecular Mechanisms of Pharmacological Action
Dopamine Agents
Neurotransmitter Agents