Identification of Biomarkers of Attention Deficit Disorder With or Without Hyperactivity (ADHD) by a Metabolomic Approach in Children (METHADA)

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03436017

Recruitment Status : Recruiting
First Posted : February 16, 2018
Last Update Posted : February 16, 2018
See **Contacts and Locations**

Sponsor:
University Hospital, Tours
Information provided by (Responsible Party):
University Hospital, Tours

Study Description

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Brief Summary:

Attention-deficit with or without hyperactivity disorder (ADHD) is a real health public concern. No easy-use diagnosis tool are available. Metabolomic approaches has brought very usefull data in others neurological diseases like amyotrophic lateral sclerosis or autism spectrum disorder, as we had shown in previous studies. Targeting on neurotransmitter pathways involving in ADHD, metabolomic screening could help to enhance our diagnosis power to better help numerus of children. We propose to study the phenylalanine and the tyrosine pathways with a multimodal metabolomic approach, in easy-available biological fluid (blood and urine), in child or adolescent suspected of ADHD. Our objectives are: 1- to determine a specific metabolomic signature of ADHD 2- to compare the diagnostic value of this metabolomic signature with the reference methodology for ADHD diagnosis, as now practiced in our reference center for learning troubles.

Condition or disease	
Adhd	Other: Metabolomic

Study Design

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Study Type :	Observational
Estimated Enrollment :	80 participants
Observational Model:	Other
Time Perspective:	Prospective

Official Title:	Identification of Biomarkers of Attention Deficit Disorder With or Without Hyperactivity (ADHD) by a Metabolomic Approach in Children
Actual Study Start Date :	November 7, 2017
Estimated Primary Completion Date :	November 2020
Estimated Study Completion Date :	November 2020

Resource links provided by the National Library of Medicine
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

U.S. FDA Resources

Groups and Cohorts
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Group/Cohort	Intervention/treatment
ADHD Patient with ADHD diagnosis criterion. The aim is the identification of Biomarkers of ADHD by a Metabolomic Approach	Other: Metabolomic approach Biological samples (blood and urine) for a multimodal metabolomic approach
non ADHD Patient with symptom of hyperactivity and/or attention deficiency but without ADHD diagnosis criterion. The aim is the identification of Biomarkers of ADHD by a Metabolomic Approach.	Other: Metabolomic approach Biological samples (blood and urine) for a multimodal metabolomic approach

Outcome Measures
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Primary Outcome Measures :

1. ADHD metabolomic's signature of blood [Time Frame: At baseline]

   Detection of metabolites (phenylalanine or catécholamines) in the blood of patients with ADHD at levels significantly different from baseline levels in the general population and rates found in patients with attention deficit and / or hyperactivity disorders but that multidisciplinary assessment excludes the diagnosis of ADHD.

2. ADHD metabolomic's signature of urine [Time Frame: At baseline]

   Detection of metabolites (phenylalanine or catécholamines) in the urine of patients with ADHD at levels significantly different from baseline levels in the general population and rates found in patients with attention deficit and / or hyperactivity disorders but that multidisciplinary assessment excludes the diagnosis of ADHD.

Biospecimen Retention: Samples Without DNA
Blood samples Urinary samples

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:	6 Years to 15 Years (Child)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No
Sampling Method:	Non-Probability Sample

Study Population

Child or adolescent with symptoms of attention disorders and / or hyperactivity, aged from 6 to 15 years old, and consulting in current care in our university hospital

Criteria

Inclusion Criteria:

- Child or adolescent with symptoms of attention disorders and / or hyperactivity
- aged from 6 to 15 years old

Exclusion Criteria:

- Failure or refusal of all or part of the multidisciplinary evaluation (medical and / or neuropsychological assessments and / or biological assessments)
- Identification of an intercurrent condition likely to have an impact on metabolomic analyzes (acute infection, fever, etc.)
- Parents or legal guardians opposed to data processing

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03436017***

Contacts

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Locations

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Sponsors and Collaborators

University Hospital, Tours

Investigators

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More Information
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Responsible Party:	University Hospital, Tours
ClinicalTrials.gov Identifier:	NCT03436017 History of Changes
Other Study ID Numbers:	RIPH3-RNI17/METHADA
First Posted:	February 16, 2018 Key Record Dates
Last Update Posted:	February 16, 2018
Last Verified:	February 2018

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

Keywords provided by University Hospital, Tours:
adhd
metabolomics
child

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders