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: NCT03447223

Recruitment Status: Not yet recruiting
First Posted: February 27, 2018
Last Update Posted: February 27, 2018

Sponsor:
Xijing Hospital

Information provided by (Responsible Party):
Xijing Hospital

Study Description

Brief Summary:
Host-microbe interactions play a key role in brain development and function and in the etiology of neurodevelopmental disorders. Attention-deficit/hyperactivity disorder (ADHD) is a heterogeneous disorder that affects 1 in 20 children and results in poor life-time outcomes. However, the etiology of ADHD is unclear and its diagnosis and treatment are still challenging. Different factors reported to be associated with the risk of developing ADHD and/or linked to different ADHD manifestations have also been linked to shifts in gut microbiota composition, suggesting a link between the microbiota and the disorder. Here, we will perform a metagenome-wide association study and serum metabolomics profiling in a cohort of control and ADHD, 3-15 years, Chinese individuals. We aim to identify ADHD-associated gut microbial species linked to changes in circulating metabolites. We also aim to find the possible intervention strategy in ADHD by targeting the gut microbiota.

Study Design

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Study Type: Observational
Estimated Enrollment: 400 participants
Observational Model: Cohort
Time Perspective: Retrospective
Official Title: Gut Microbiome and Serum Metabolome Alterations in Attention-deficit/Hyperactivity Disorder Patients

Anticipated Study Start Date : February 28, 2018

Estimated Primary Completion Date : February 27, 2020

Estimated Study Completion Date : February 27, 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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<table>
<thead>
<tr>
<th>Group/Cohort</th>
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</thead>
<tbody>
<tr>
<td>ADHD-patients</td>
</tr>
<tr>
<td>The children 3-15 years old with ADHD. Diagnoses of the children with ADHD were made in Xijing Hospital according to criteria described in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). Children with ADHD had an IQ score above 70.</td>
</tr>
</tbody>
</table>

| Controls-healthy children    |
| Age- and gender- matched healthy 3-15 years old children. |

Outcome Measures

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Primary Outcome Measures :
   metagenome

Secondary Outcome Measures :
1. serum metabolomics profiling [Time Frame: 2018-2019 ]
   metabonomics

Biospecimen Retention: Samples With DNA
whole blood samples: serum metabolomics analyses; faeces: gut metagenome analyses

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: 3 Years to 15 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: Yes
Sampling Method: Probability Sample

Study Population
All subjects were drug-naive at the time of recruitment, and the ADHD tests were administered before the subjects were given any medication. The subjects will be recruited from Xijing Hospital and elementary and secondary schools in China.

Criteria

Inclusion Criteria:
Diagnoses of the children with ADHD were made in Xijing Hospital according to criteria described in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). Children with ADHD had an IQ score above 70.

Exclusion Criteria:
Children who had a past history of or were currently affected by neurological diseases, including convulsive disorders or brain damage; or who had any evidence of comorbid psychiatric conditions, such as Tourette's syndrome, IQ below 70, pervasive developmental disorder (autism), bipolar disorder, psychosis, language difficulties or learning disorders (reading disorders, mathematics disorders and disorders of written expression).

Contacts and Locations

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): NCT03447223

Contacts
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Sponsors and Collaborators
Xijing Hospital

Investigators
Principal Investigator: Lize Xiong, M.D./Ph.D. Professor and President, Xijing Hospital

More Information

Additional Information:
Wikipedia

Publications:
Responsible Party: Xijing Hospital
ClinicalTrials.gov Identifier: NCT03447223
Other Study ID Numbers: KY20182002-1
First Posted: February 27, 2018
Last Update Posted: February 27, 2018
Last Verified: January 2018

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

Keywords provided by Xijing Hospital:
Attention-deficit/hyperactivity disorder
circulating metabolites
metagenome

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity Mental Disorders
Congenital Microtia Ear Diseases
Attention Deficit and Disruptive Behavior Disorders Otorhinolaryngologic Diseases
Neurodevelopmental Disorders Congenital Abnormalities