Candidate Gene Screening for Attention Deficit/Hyperactive Disorder (ADHD)

This study has been completed.

Sponsor:
Xijing Hospital

Collaborator:
Soochow University

Information provided by (Responsible Party):
Xijing Hospital

ClinicalTrials.gov Identifier:
NCT03018574

First received: January 11, 2017
Last updated: NA
Last verified: January 2017
History: No changes posted

Purpose

Source: Sample bank of Xijing Hospital and Children's Hospital Affiliated to Soochow University; Sample form: Whole blood; Estimated number of samples: 100 patients with ADHD and age, sex matched healthy controls; Case exclusion criteria: all kinds of neuropsychiatric disorders, IQ value of less than 70;

Study protocol:

1. Using Qiagen kit to extract the genomic DNA of 200 microliters of blood.

2. UV spectrophotometer test DNA purity of 260/280 close to 1.8 (1.8 ± 0.05), the concentration of 100ng/μL or more before the next sequencing.

3. The extracted genomic DNA will be sent to Sangon Biology Engineering Limited Company (Shanghai) and sequenced to find candidate mutations related to ADHD risk sequence. According to NIH gene database, the longest transcript of NDRG2 (ID: 57447 gene, https://www.ncbi.nlm.nih.gov/nuccore/NC_000014.9?Report=genbank&from=21016763&to=21070872&strand=true) (a total of 17 exons and 16 introns and the gene 5 'UTR and 3' UTR region) will be alignmented sequences to find potential mutations.

4. Using the chi square analysis and other statistical methods to determine the relationship between the mutations and susceptibility to ADHD.

<table>
<thead>
<tr>
<th>Condition</th>
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<tbody>
<tr>
<td>Gene Product Sequence Variation</td>
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</table>
Study Type: Observational

Study Design: Observational Model: Case Control
Time Perspective: Retrospective

Official Title: Candidate Gene Screening for 6-14 Year Old Patients With ADHD (Attention Deficit/Hyperactivity Disorder)

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder Genes and Gene Therapy

U.S. FDA Resources

Further study details as provided by Xijing Hospital:

Primary Outcome Measures:

- The relationship between candidate mutations with ADHD risk [Time Frame: 2016-2017]
  [Designated as safety issue: Yes]

Biospecimen Retention: Samples With DNA
Whole blood

Enrollment: 100

Study Start Date: May 2016

Study Completion Date: January 2017

Primary Completion Date: January 2017 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Groups/Cohorts</th>
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<tbody>
<tr>
<td>ADHD-patients</td>
</tr>
<tr>
<td>The whole blood sample from diagnoses of the children 6-14 years old with ADHD. Diagnoses of the children with ADHD were made in Xijing Hospital and Children's Hospital Affiliated to Soochow University 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       |
| The whole blood sample from age- and gender- matched healthy 6-14 years old children |

Detailed Description:
Source: Sample bank of Xijing Hospital and Children's Hospital Affiliated to Soochow University; Sample form: Whole blood; Estimated number of samples: 100 patients with ADHD and age, sex matched healthy controls; Case exclusion criteria: all kinds of neuropsychiatric disorders, IQ value of less than 70;

Study protocol:

1. Using Qiagen kit to extract the genomic DNA of 200 microliters of blood. (1) melt frozen blood at room temperature; (2) take the blood of 0.2 ml into a sterile anti coagulation centrifuge tube, add an equal volume of PBS phosphate buffer, after fully mixing 12000rpm centrifugation 5min, discard supernatant; (3) 66.7 L STE 2.4 L, 20% SDS, 37 DEG C water bath 1h; (4) protease K plus 1 20mg/ml l mix, 55 DEG C water bath digestion overnight (10 ~ 14h); (5) the digested samples treated with Tris saturated phenol, shake well, 12000rpm centrifugal 10min; (6) the upper aqueous phase to a sterile centrifuge tube; adding volume of Tris saturated phenol, shake well, 12000rpm centrifugal 10min; (7) the upper aqueous phase was transferred to another sterile centrifuge tube, and an equal volume of phenol was added: chloroform: isoamyl alcohol (25: 24: 1). The oscillation of the vortex was fully mixed, and the 12000rpm was centrifuged to 10min; (8) the upper aqueous phase was transferred to another sterile centrifuge tube, and an equal volume of chloroform was added: isoamyl alcohol (24: 1), which was fully vibrated and mixed with 12000rpm centrifugation 10min; (9) transfer the supernatant to another sterile centrifuge tube; adding 2 times volume ethanol, the volume level of sodium acetate 1/10 shake, until the flocculent precipitation of DNA visible; (10) the sample is placed at -20 DEG C refrigerator freezer 30min or ice bath for 15 ~ 20min, after removal of 12000rpm centrifugal 10min again, so that DNA precipitation; (11) the gun head will pick DNA to another sterile centrifuge tube, with the amount of 70% ethanol washing and shaking, to wash out impurities DNA; (12) out of ethanol, DNA by vacuum drying or dry naturally, TE buffer adding dissolution, -20 stored at standby.

2. UV spectrophotometer test DNA purity of 260/280 close to 1.8 (1.8 ± 0.05), the concentration of 100ng/μL or more before the next sequencing.

3. The extracted genomic DNA will be sent to Sango Biology Engineering Limited Company (Shanghai) and sequenced to find candidate mutations related to ADHD risk sequence. According to NIH gene database, the longest transcript of NDRG2 (ID: 57447 gene, https://www.ncbi.nlm.nih.gov/nuccore/NC_000014.9?Report=genbank&from=21016763&to=21070872&strand=true) (a total of 17 exons and 16 introns and the gene 5 'UTR and 3' UTR region) will be alignmented sequences to find potential mutations.

4. Using the chi square analysis and other statistical methods to determine the relationship between the mutations and susceptibility to ADHD.

Eligibility

Ages Eligible for Study: 6 Years to 14 Years (Child)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes
Sampling Method: Probability Sample

Study Population

Diagnoses of the children with ADHD were made in Xijing Hospital and Children's Hospital Affiliated to Soochow University according to criteria described in the Diagnostic and Statistical Manual of Mental Disorders. Children with ADHD had an IQ score above 70.

Criteria
Inclusion Criteria:

- Diagnoses of the children with ADHD were made in Xijing Hospital and Children's Hospital Affiliated to Soochow University 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
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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT03018574

Locations

China, Shaanxi

Xijing Hospital of the Fourth Military Medical University
Xi'an Shi, Shaanxi, China, 710032

Sponsors and Collaborators

Xijing Hospital
Soochow University

Investigators

Principal Investigator: Yan Li, PhD&MD Xijing hospital of The fourth military medical university

More Information

Publications:


Responsible Party: Xijing Hospital
ClinicalTrials.gov Identifier: NCT03018574

Other Study ID Numbers: KY20163381

Study First Received: January 11, 2017

Last Updated: January 11, 2017

Health Authority: China: Food and Drug Administration

Individual Participant Data

Plan to Share IPD: Yes

Plan Description: Publish all data in a paper

Additional relevant MeSH terms:

Attention Deficit Disorder with Hyperactivity
Attention Deficit and Disruptive Behavior Disorders
Neurodevelopmental Disorders
Mental Disorders

ClinicalTrials.gov processed this record on January 12, 2017