Omega-3 Polyunsaturated Fatty Acids in Youth With ADHD

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. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT03542643

Recruitment Status: Completed
First Posted: May 31, 2018
Last Update Posted: May 31, 2018

Sponsor:
China Medical University Hospital

Collaborators:
National Science Council, Taiwan
King's College London

Information provided by (Responsible Party):
China Medical University Hospital

Study Description

Go to Brief Summary:

N-3 polyunsaturated fatty acids (N-3 PUFAs) is important in balancing the immune function and crucial for the developing brain. Deficiency in n-3 PUFAs might be linked to the poor cognitive performances resulting in inattention and hyperactivity in youth with attention deficit hyperactivity disorder (ADHD). N-3 PUFAs appears to be a promising treatment that is safe, beneficial to youth with ADHD. In this proposal, investigators aim the test the hypothesis that n-3 polyunsaturated fatty acids will be more effective than placebo in improving cognitive function in youth with ADHD after 12 weeks of intervention.

Condition or disease

<table>
<thead>
<tr>
<th>Attention Deficit Hyperactivity Disorder</th>
<th>ADHD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dietary Supplement: n-3 Polyunsaturated</td>
<td>Fatty Acids</td>
</tr>
</tbody>
</table>

Detailed Description:

This is a 1-year study and a randomized, double-blind, and placebo controlled Clinical the study. investigators plan to enrol 100 subjects from Child and Adolescent Psychiatry Outpatient Clinic of China Medical University Hospital. Participants will be randomized into omega-3 polyunsaturated fatty acids or placebo group. The intervention period is 12 weeks. Evaluation of the cognitive function (using Continuous Performance Test 3rd Edition) of the subjects who are enrolled into the study will take place at baseline and after the 12th week. The symptom severity of ADHD will be measured with Swanson, Nolan, Pelham Questionnaire (SNAP-IV) at baseline, 2, 4, 8, and 12 weeks. The plasma level of n-3 polyunsaturated fatty acids, blood and salivary inflammatory markers will also be measured at the beginning and at the end of the study.

Study Design

Go to

Study Type: Interventional (Clinical Trial)
Actual Enrollment: 105 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: A Double-blind Randomised Controlled Trial of N-3 PUFAs in Children With Attention Deficit Hyperactivity Disorder

Actual Study Start Date: July 7, 2016

Actual Primary Completion Date: December 11, 2017

Actual Study Completion Date: December 11, 2017

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

Drug Information available for: Omega-3 Fatty Acids

U.S. FDA Resources

Arms and Interventions

<table>
<thead>
<tr>
<th>Arm</th>
<th>Intervention/treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Comparator: N-3 polyunsaturated fatty acids</td>
<td>Dietary Supplement: n-3 Polyunsaturated fatty acid 1g of Eicosapentaenoic acid (EPA)</td>
</tr>
<tr>
<td>n-3 polyunsaturated fatty acids dosage of 1g of Eicosapentaenoic acid (EPA)</td>
<td></td>
</tr>
<tr>
<td>Placebo Comparator: Placebo olive oil ethyl esters</td>
<td>Dietary Supplement: Placebo Olive oil ethyl esters</td>
</tr>
</tbody>
</table>

Outcome Measures

Primary Outcome Measures:
1. Changes in Continuous Performance Test Raw Scores at 12 weeks [Time Frame: Week 0 and Week 12]

Secondary Outcome Measures:
1. Changes in SNAP-IV Scores for Inattention, Hyperactivity and Total ADHD Symptom Severity [Time Frame: Week 0, 2, 4, 8, 12]

Other Outcome Measures:
1. Changes in Blood PUFAs levels at 12 Weeks [Time Frame: Week 0 and Week 12]
2. Changes in Blood Inflammatory Markers at 12 Weeks [Time Frame: Week 0 and Week 12]
3. Changes in Salivary Cortisol at 12 Weeks [Time Frame: Week 0 and Week 12]

Eligibility Criteria

Go to ▼
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 18 Years  (Child, Adult)
**Sexes Eligible for Study:** All
**Accepts Healthy Volunteers:** No

**Criteria**

**Inclusion Criteria:**
- DSM-5 diagnosed ADHD
- Age 6-18 years old at time of enrolment
- Conner’s rating scales (CPRS) with scores >= 2 standard deviations
- Drug native or no medication use for past 6 months
- Signed informed consent

**Exclusion Criteria:**
- Intelligence quotient <70
- Comorbid other psychiatric disorders, such as autism spectrum disorders, anxiety disorders, conduct disorders, schizophrenia, major depressive disorders and bipolar spectrum disorders
- Comorbid physical disorders, such as thyroid dysfunction, cerebral palsy
- Current using omega-3 supplements
- Allergy to omega-3

**Contacts and Locations**

Go to ▼

**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): NCT03542643

**Locations**

Taiwan
China Medical University
Taichung, Taiwan, 404

**Sponsors and Collaborators**

China Medical University Hospital
National Science Council, Taiwan
King’s College London

**More Information**

Go to ▼

Responsible Party: China Medical University Hospital
ClinicalTrials.gov Identifier: NCT03542643  History of Changes
Other Study ID Numbers: CMUH104-REC2-058