Efficacy Study of Vayarin in Children With Autism and Comorbid Attention Deficit Hyperactivity Disorder (ADHD)

This study is currently recruiting participants. (see Contacts and Locations)

Verified April 2017 by Institute of Mental Health, Singapore

Sponsor:
Institute of Mental Health, Singapore

Information provided by (Responsible Party):
Dr Sung Min, Institute of Mental Health, Singapore

ClinicalTrials.gov Identifier:
NCT03115671

First received: April 12, 2017
Last updated: NA
Last verified: April 2017
History: No changes posted

Purpose

This research study is carried out to examine the effects of Phosphatidylserine-Omega 3 supplements (i.e., Vayarin) among children with Autism Spectrum Disorder (ASD) and ADHD. Participants will be randomised either to receive the Vayarin treatment (Intervention group) or to a Control group.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autism Spectrum Disorder</td>
<td>Dietary Supplement: Vayarin</td>
</tr>
<tr>
<td>Attention Deficit Hyperactivity Disorder</td>
<td></td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design:
Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Outcomes Assessor
Masking Description:
Clinicians conducting the study assessments and teachers who will be providing feedback will be blinded to the study arm.

Primary Purpose: Treatment
Official Title: An Open-label Pilot Study on the Efficacy of Phosphatidylserine-Omega 3 (Vayarin) in Pediatric Patients Diagnosed With Autism and Comorbid Attention Deficit Hyperactivity Disorder (ADHD)

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder

Drug Information available for: Omega-3 Fatty Acids

U.S. FDA Resources

Further study details as provided by Institute of Mental Health, Singapore:

Primary Outcome Measures:

- Conners 3rd Edition - Parent [Time Frame: 12 weeks]
  Changes from baseline to Week 12 on Conners 3rd Edition - Parent

- Social Responsiveness Scale (SRS) [Time Frame: 12 weeks]
  Changes from baseline to Week 12 on Social Responsiveness Scale (SRS)

- Aberrant Behaviour Checklist (ABC) [Time Frame: 12 weeks]
  Change from baseline to Week 12 on the Aberrant Behaviour Checklist (ABC), specifically on irritability subscale

Secondary Outcome Measures:

- Physical examination and safety evaluation (PAERS) [Time Frame: 12 weeks]
  Assessments of related side effects and adverse events of the supplements based on physical examination and safety evaluation (as measured by PAERS) at baseline, Week 6 and 12

Estimated Enrollment: 50

Actual Study Start Date: November 30, 2016

Estimated Study Completion Date: September 2017

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

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental: Intervention</td>
<td>Dietary Supplement: Vayarin</td>
</tr>
<tr>
<td>Each child participant in the Intervention group will be taking 4 capsules of Vayarin</td>
<td>Vayarin</td>
</tr>
</tbody>
</table>
per day for 3 months. Each capsule contains 167mg Lipirinen, providing 75mg Phosphatidylserine (PS), 21.5mg EPA and 8.5mg DHA. This gives a daily dosage of 300mg PS and 120mg EPA/DHA. They may continue their treatment as usual provided there is no change in medication and intervention during the trial.

Vayarin capsule
Other Name:
Phosphatidylserine-omega-3 (Lipirinen)

No Intervention: Control
Participants in the Control group will not be given Vayarin. They may continue their treatment as usual provided there is no change in medication and intervention during the trial.

Detailed Description:

There has been growing interest in the role of supplements such as omega-3 polyunsaturated fatty acids (n-3 PUFAs) in ADHD and ASD. Two of the primary n-3 PUFAs are eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which are critical to brain development and are usually obtained through our diets. Increasing evidence has shown that children with ASD and/or ADHD have lower overall blood n-3 PUFAs levels than typically developing children (Parletta, Niyonsenga & Duff, 2016). Therefore, many studies have been conducted to examine the effectiveness of n-3 PUFAs supplementation among these two populations. While these supplements were found to have small but reliable benefit on ADHD symptoms (Hawkey & Nigg, 2014), there is limited evidence to support the use of n-3 PUFAs in clinical practice for the treatment of behavioural symptoms in children with ASD (James, Montgomery & Williams, 2011; Roux, 2015). Such inconsistencies give rise to the exploration of other alternatives in administering n-3 PUFAs.

Phosphatidylserine (PS), an acidic phospholipid (PL) molecule, comprises of a glycerol backbone esterified to the hydroxyl group of the amino acid serine via a phosphate group and to two fatty acids moiety (Manor et al., 2012). It plays a key role in the functioning of neuron membranes and may enhance the bioavailability of PUFAs. Administration of PL containing omega-3 PUFAs showed greater improvement in visual sustained attention performance among school children with ADHD, as compared to placebo and fish oil groups (Vaisman et al., 2008). Similarly, another study also suggested the benefits of PS-Omega3 (i.e., Vayarin) in reducing ADHD symptoms (Manor et al., 2012). This supplementation is shown to be generally safe and well-tolerated (Manor et al., 2013).

Nevertheless, these studies were conducted among children with ADHD. Given that n-3 PUFAs are commonly used by children with comorbid ASD and ADHD, there is a need to examine whether similar effects can be observed in this population. The goal of our present study is to examine the effect of PS-Omega3 supplement among children with comorbid ASD and ADHD. The safety and tolerability will also be assessed in this pilot trial.

Eligibility

Ages Eligible for Study: 6 Years to 12 Years (Child)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Between the age of 6 and 12 years old inclusive.
- Meets diagnostic criteria for ASD, based on Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), verified by Autism Diagnostic Observation Scale (ADOS).
- Meets diagnostic criteria for ADHD (hyperactive/inattentive/combined subtype), based on Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5).
- Clinical Global Impression Scale of Severity of illness (CGI-S) rating of 4 and above.
- Potential participants who are on stimulatory prescriptions should have no dose change 3 months prior to study initiation and throughout the study.
- Potential participants who are on other omega supplements to stop the supplements prior to the initiation and throughout the study.
- Potential participants who are on behavioural interventions should have no change in frequency or treatment plan 3 months prior to study initiation and throughout the study.

**Exclusion Criteria:**

- Girls who have reached menarche and presented with 3 previous regular menstrual cycles to minimize risk of adverse side effects.
- Change in dosage of psychiatric pharmacotherapy or other medications that have central nervous system effects or that affect performance, e.g., antidepressants (e.g. SSRIs, SNRIs), antipsychotics, adrenergic blockers, decongestant or sympathomimetics, anticonvulsants, mood stabilizers, melatonin, and sedating anti-histamines, or lithium carbonate 3 months before study initiation and throughout the study phase.
- Patients that would be contraindicated for Aspirin and Warfarin treatment or present with known allergic reactions or sensitivity to marine, soy or corn products, or any other illness that the clinician determines may jeopardize patient's health.
- Patients with a known genetic syndrome which may complicate the presentation of ASD (e.g. Fragile X, William's Syndrome, Prader-Willi etc.) or presenting with suspected brain or central nervous system condition.
- Patients who present with symptoms of psychosis or high risk condition such as mood issues and suicide risk or present with history of physical, sexual or emotional abuse
- Patients who are significantly underweight (under 5th percentile) or overweight (above the 95th percentile) for his age.
- Patients who did not adhere to the study procedures

**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: NCT03115671

**Contacts**

Contact: Tze Jui Goh  +6564353861  tze_jui_goh@imh.com.sg
Contact: Yi Ren Tan  +6564353975  yi_ren_tan@imh.com.sg

**Locations**

Singapore

Child Guidance Clinic  Recruiting
Singapore, Singapore, 168937
Contact: Tze Jui Goh  +6564353861  tze_jui_goh@imh.com.sg
Contact: Yi Ren Tan  +64353975  yi_ren_tan@imh.com.sg
Principal Investigator: Min Sung, Dr

**Sponsors and Collaborators**
Institute of Mental Health, Singapore

**Investigators**
Principal Investigator:  Min Sung, Dr  Institute of Mental Health, Singapore

**More Information**

Publications:

Responsible Party:  Dr Sung Min, Senior Consultant, Institute of Mental Health, Singapore
ClinicalTrials.gov Identifier:  NCT03115671  History of Changes
Other Study ID Numbers:  DSRB A/16/01120
CTC 1600529 ( Other Identifier: Health Sciences Authority )
Study First Received:  April 12, 2017
Last Updated:  April 12, 2017

Individual Participant Data
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 Institute of Mental Health, Singapore:
Phosphatidylserine
Omega-3

Additional relevant MeSH terms:
Disease  Neurodevelopmental Disorders
Autistic Disorder  Mental Disorders
Attention Deficit Disorder with Hyperactivity  Attention Deficit and Disruptive Behavior Disorders
Hyperkinesis  Dyskinesias
Autism Spectrum Disorder
Pathologic Processes
Child Development Disorders, Pervasive

Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms

ClinicalTrials.gov processed this record on April 14, 2017