Effects of Polyphenolic Extract From Pine Bark on the Inattention and Hyperactivity in Patients With Attention Deficit Hyperactivity Disorder Based on the Antioxidative Status.

This study is currently recruiting participants.

See ▶ Contacts and Locations

Verified June 2017 by Taipei Medical University

Sponsor:
Taipei Medical University

ClinicalTrials.gov Identifier:
NCT03368690

First Posted: December 11, 2017
Last Update Posted: December 11, 2017

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.

Information provided by (Responsible Party):
Taipei Medical University

Purpose
In this study, the investigators will investigate the effects of polyphenolic extract from pine bark on the inattention and hyperactivity in patients with attention deficit hyperactivity disorder (ADHD) based on antioxidative status.

### Study Type
Interventional

### Study Design
Allocation: Randomized
Intervention Model: Crossover Assignment
Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Primary Purpose: Supportive Care

Official Title: Effects of Polyphenolic Extract From Pine Bark on the Inattention and Hyperactivity in Patients With Attention Deficit Hyperactivity Disorder Based on the Antioxidative Status.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADHD</td>
<td>Dietary Supplement: Oligopin® Other: Placebo</td>
</tr>
</tbody>
</table>

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder
Further study details as provided by Taipei Medical University:

Primary Outcome Measures:
- Swanson, Nolan and Pelham Teacher and Parent Rating Scale (Snap-IV) [Time Frame: Change baseline four weeks of the experiment.]
  It is used to evaluate the inattention, impulsivity and hyperactivity for children and adolescent with ADHD as rated by parents and teachers. When Inattention/Hyperactivity-impulsivity subscales approach P85, the participants are going to the next steps.

- Adult ADHD Self-Report Scale-V1.1 (ASRS-V1.1) or Individual Subjective Perception Job Stress Scale (ISPJSS) [Time Frame: Change baseline four weeks of the experiment.]
  It is used to evaluate the inattention, impulsivity and hyperactivity for adult with ADHD as rated by participants. The scores of ASRS-V1.1 more than 17, that can be going to the next steps.

- Conners' Continuous Performance Test (CPT-III) [Time Frame: Change baseline four weeks of the experiment.]
  It is used to evaluate the inattention, impulsivity and vigilance for subjects with ADHD. T-score > 60 approach clinical standard.

Secondary Outcome Measures:
- Liver function [Time Frame: Change baseline four weeks of the experiment.]
  Serum AST, ALT and bilirubin-total are in units per liter

- Kidney function [Time Frame: Change baseline four weeks of the experiment.]
  Serum BUN, Creatine and urine acid are in milligram per deciliter

- Lipid profile [Time Frame: Change baseline four weeks of the experiment.]
  Serum HDL-Cho, LDL-Cho, triglyceride and total cholesterol are in milligram per deciliter

- Hematology [Time Frame: Change baseline four weeks of the experiment.]
  Serum WBC in 1000/uL, RBC in 1000000/uL, hemoglobin in gram per deciliter, hematocrit in percentage, MCV in femtoliter, MCH in picogram, MCHC in gram per deciliter, platelet in 1000/uL; neutrophils, lymphocytes, monocytes, eosinophils and basophils are in percentage.

- Iron status [Time Frame: Change baseline four weeks of the experiment.]
  Serum iron, ferritin and TIBC are in microgram per deciliter

- Antioxidative status [Time Frame: Change baseline four weeks of the experiment.]
  Thiobarbituric acid-reactive substance and glutathione/oxidized glutathione ratio.

- Dietary history [Time Frame: Change baseline four weeks of the experiment.]
  To analyze nutrition status of participants.

- 24 hour recall method [Time Frame: Change baseline four weeks of the experiment.]
  To analyze nutrition status of participants.
- Food frequency questionnaire [Time Frame: Change baseline four weeks of the experiment.]
  To analyze nutrition status of participants.

- Three-day dietary record. [Time Frame: Change baseline four weeks of the experiment.]
  To analyze nutrition status of participants.

Estimated Enrollment: 40
Actual Study Start Date: August 30, 2017
Estimated Study Completion Date: June 30, 2019
Estimated Primary Completion Date: May 31, 2019 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
</table>
| Experimental: Oligopin®                   | Dietary Supplement: Oligopin®
Dietary supplement, Polyphenolic extract from pine bark. This group receives a nutritional supplement for a period of 10 weeks.
Children and adolescent 20-50 kg body weight: 25 mg Oligopin®/day; > 50 kg body weight: 50 mg Oligopin®/day
Adults 40-60 kg body weight: 100 mg Oligopin®/day; > 60 kg body weight: 150 mg Oligopin®/day |
| Placebo Comparator: Placebo              | Other: Placebo
Placebo treatment (identical capsules containing maltodextrin and magnesium stearate)                                                               |

Eligibility

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: 7 Years to 64 Years (Child, Adult)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:
1. Children or adolescent with attention deficit hyperactivity disorder (ADHD) whose age reach 7 but under 20 and were not treated with ADHD drugs, antihypertensive drugs and dietary supplements more than 4 weeks.

2. Adults with attention deficit hyperactivity disorder (ADHD) aged from 20 to 65 and were not treated with antihypertensive drugs and dietary supplements more than 4 weeks.

Exclusion Criteria:

1. Children or adolescent treated with ADHD drugs, antihypertensive drugs and dietary supplements
2. Adults treated with antihypertensive drugs and dietary supplements
3. Nervous system diseases (including brain or other central nervous system diseases, e.g. epilepsy)
4. Autism spectrum disorder
5. Intellectual disability
6. Other mental disorders (e.g. Schizophrenia, Bipolar Disorder, Major depressive disorder, Anxiety Disorder, Personality disorders, Conduct disorder, Tourette Syndrome.)
7. Hepatic, renal, gastrointestinal and cardiovascular disorders
8. Biochemical abnormality

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): NCT03368690

Contacts

Contact: Suh-Ching Yang  +886-2-2736-1661 ext 6553  sokci@tmu.edu.tw

Locations

Taiwan

Taipei Medical University - Shuang Ho Hospital  Recruiting
New Taipei City, Taiwan, 23561
Contact: I-Cheng Lin  886-2-22490088 ext 79212  12023@s.tmu.edu.tw

Taiwan Adventist Hospital  Recruiting
Taipei City, Taiwan, 10556
Contact: Alex Su  886-2-27718151 ext 2692  alexhsu588@yahoo.com.tw

Sponsors and Collaborators
Taipei Medical University

More Information

Responsible Party: Taipei Medical University
ClinicalTrials.gov Identifier: NCT03368690  History of Changes
Other Study ID Numbers: N201706026
First Submitted: August 14, 2017
First Posted: December 11, 2017
Last Update Posted: December 11, 2017
Last Verified: June 2017
Individual Participant Data (IPD) Sharing Statement:

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 Taipei Medical University:
Polyphenolic extract from pine bark, Antioxidant, Attention deficit/hyperactivity disorder.

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

Dyskinesias
Neurologic Manifestations
Nervous System Diseases
Signs and Symptoms