Taurine as an Anti-manic Agent: a Double-blind Placebo-controlled Study.

**Sponsors**

**Lead Sponsor**
Mclean Hospital

**Source**
Mclean Hospital

**Oversight Info**
**Authority**
United States: Food and Drug Administration

**Brief Summary**
The purpose of this study is to determine whether the amino acid taurine has effects on mood stability in bipolar disorder.

**Detailed Description**
Taurine is an amino acid that has some actions similar to mood stabilizers. Taurine is widely sold as a component of over-the-counter mood enhancing agents. However, controlled studies examining the mood effects of taurine are limited. An initial study in this laboratory looked at taurine’s mood effects in individuals with bipolar disorder. This follow-up study is designed to further examine taurine’s effects on manic symptoms. Subjects in the current follow-up study will add taurine or placebo to their current treatment regimen. Both depressive and manic symptoms will be tracked for three months to determine whether the addition of taurine affects mood symptoms.

**Overall Status**
Completed

**Start Date**
2005-04-01

**Completion Date**
2011-12-01

**Primary Completion Date**
2010-01-01

**Phase**
Phase 2

**Study Type**
Interventional

**Study Design**
Allocation: Randomized, Endpoint Classification: Efficacy Study, Intervention Model: Parallel Assignment, Masking: Double Blind (Subject, Investigator, Outcomes Assessor), Primary Purpose: Treatment

**Primary Outcome**
**Measure**
Scores on standardized measures of manic and depressive symptoms (HAM-D, MADRS, YMRS)

**Time Frame**
12 weeks

**Safety Issue**
No

**Secondary Outcome**
**Measure**
Side-effect ratings, general health ratings (SF36)

**Time Frame**
12 weeks

**Safety Issue**
No

**Drop-outs due to medication changes**

**Time Frame**
12 weeks

**Safety Issue**
No

**Enrollment**
60

**Conditions**
Bipolar Disorder, Mania, Bipolar Depression

**Intervention**
**Intervention Type**
Drug

**Intervention Name**
Taurine

**Description**
taurine 2mg BID po

**Arm Group Label**
1

**Eligibility**
**Criteria**
Inclusion Criteria:
bipolar disorder, type I bipolar disorder, type II mania hypomania mixed manic symptoms

Exclusion Criteria:
significant medical or psychiatric co-morbidity pregnancy or planning pregnancy current substance abuse or dependence

**Gender**
Both

**Minimum Age**
18 Years

**Maximum Age**
68 Years

**Healthy Volunteers**
No

**Overall Official**
**Last Name**
Beth L Murphy, MD, PhD

**Role**
Principal Investigator

**Affiliation**
Mclean Hospital

**Location**
Facility

http://ichgcp.net/clinical-trials-registry/NCT00217165
<table>
<thead>
<tr>
<th>Location Countries</th>
<th>Country</th>
<th>United States</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verification Date</td>
<td>2014-06-01</td>
<td></td>
</tr>
<tr>
<td>Lastchanged Date</td>
<td>2014-06-02</td>
<td></td>
</tr>
<tr>
<td>Firstreceived Date</td>
<td>2005-08-22</td>
<td></td>
</tr>
<tr>
<td>Responsible Party Type</td>
<td>Principal Investigator</td>
<td></td>
</tr>
<tr>
<td>Investigator Affiliation</td>
<td>Mclean Hospital</td>
<td></td>
</tr>
<tr>
<td>Investigator Full Name</td>
<td>Beth L. Murphy MD, PhD</td>
<td></td>
</tr>
<tr>
<td>Investigator Title</td>
<td>Principal Investigator</td>
<td></td>
</tr>
<tr>
<td>Keywords</td>
<td>bipolar, mania, depression, taurine, alternative</td>
<td></td>
</tr>
<tr>
<td>Is Fda Regulated</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Has Expanded Access</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Condition Browse</td>
<td>Depression, Bipolar Disorder</td>
<td></td>
</tr>
<tr>
<td>Number Of Arms</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Intervention Browse</td>
<td>Antimanic Agents</td>
<td></td>
</tr>
<tr>
<td>Is Section 801</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Arm Group</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Arm Group Type</td>
<td>Placebo Comparator</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>drug</td>
<td></td>
</tr>
<tr>
<td>Firstreceived Results Date</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>Firstreceived Results Disposition Date</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

ClinicalTrials.gov processed this data on September 13, 2016

© 2017 ICH GCP