Protocol Registration Receipt
07/30/2008

Placebo Controled Clinical Trial Using Topiramate To Treat Posttraumatic Stress Disorder (PTSD) Patients. (TOPIRAMATEPTSD)

This study is currently recruiting participants.
Verified by Federal University of São Paulo, July 2008

<table>
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<tr>
<th>Sponsored by:</th>
<th>Federal University of São Paulo</th>
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<tr>
<td></td>
<td>Fundação de Amparo à Pesquisa do Estado de São Paulo</td>
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<th>Federal University of São Paulo</th>
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<tr>
<th>Clinical Trials.gov Identifier:</th>
<th>NCT00725920</th>
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**Purpose**

The study is 12-week randomized placebo controlled trial compared to topiramate to treat patients with posttraumatic stress disorder, according to DSM-IV criteria.

Patients will receive topiramate or placebo, the dose will start with 25 mg/day and every week 25mg will be increment according to patients tolerance to side effects.

Patients will be evaluated by blind raters using CAPS, BDI, BAI, SF-36 and SAS. the outcomes will be improvement on PTSD, Depression, Anxiety, quality of life and social adjustment scale according to scales above.

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<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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<tbody>
<tr>
<td>Posttraumatic Stress Disorder</td>
<td>Drug: topiramate</td>
<td>Phase 4</td>
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<tr>
<td></td>
<td>Drug: placebo</td>
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**Study Type:** Interventional

**Study Design:** Treatment, Parallel Assignment, Double Blind (Subject, Investigator, Outcomes Assessor), Randomized, Placebo Control, Efficacy Study

**Official Title:** Randomized Clinical Trial to Study the Topiramate Efficacy for Posttraumatic Disorder Treatment
Further study details as provided by Federal University of São Paulo:

Primary Outcome Measure:
- Clinician Administered Posttraumatic Stress Disorder Scale  [Time Frame: 12 week] [Designated as safety issue: No]

Secondary Outcome Measures:
- SF-36  [Time Frame: 12 week] [Designated as safety issue: No]

Estimated Enrollment: 72
Study Start Date: January 2007
Estimated Study Completion Date: January 2009
Estimated Primary Completion Date: January 2009

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<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tr>
<td>Experimental: 1</td>
<td>Drug: topiramate</td>
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<tr>
<td>patients receiving the active drug:</td>
<td>patients will receive the active drug</td>
</tr>
<tr>
<td>topiramate</td>
<td></td>
</tr>
<tr>
<td>Placebo Comparator: 2</td>
<td>Drug: placebo</td>
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</table>

Seventy-two (72) patients will be randomly allocated, in a stratified manner, according to sex and comorbidity with depression, into two (2) groups: topiramate and routine clinical follow-up, and a group that would receive placebo pills and routine clinical follow-up. The patients will be submitted to evaluations by trained independent researchers, who will apply a structured clinical interview for DSM-IV in order to evaluate the presence of psychiatric disorders (SCID I and SCID-II); the scale of evaluation of the Impact Event Scale-IES; the frequency and intensity of the symptoms of PTSD and of the variations associated with the trauma (PTSD Scale administered by clinical personnel: “Clinician-Administered PTSD Scale” - CAPS); severity of depression: Beck Depression Inventory (BDI) and that of anxiety: Beck Anxiety Inventory (BAI); a scale for the evaluation of social adaptation: Social Adjustment Scale (SAS); a scale for the evaluation of Quality of Life: SF-36; a scale for the evaluation of global functioning – axis V of DSM-IV (AGF). The patients will receive active treatment for twelve (12) weeks. After this period, the patients who have been using topiramate and who have had an improvement in their clinical condition will continue to receive further treatment for another twelve (12) weeks. Patients will have their medication suspended after twenty four (24) weeks and will be followed-up for a further twenty four (24) weeks. Patients from the placebo group who showed improvement will continue to receive clinical follow-up for a further thirty six (36) weeks. Patients from the placebo group who showed a worsening in their clinical status, evaluated through the CGI, will be excluded from the study and sent for traditional treatment at the PROVE (Violence and Stress Program) clinic. Patients who terminated the active phase of the study who did not obtain a clinical improvement will be sent for traditional treatment at the PROVE clinic. The principal outcomes to be examined will be: Response (a decrease of 50% in the CAPS score starting from the baseline) and remission (lack of diagnostic criteria for PTSD in the CAPS). After the end of the treatment, the collected data will be tabulated and compared using parametric and non-parametric tests. In this study the validation of the CAPS scale for Portuguese will be carried out.
Eligibility

Ages Eligible for Study: 18 Years to 65 Years
Genders Eligible for Study: Both

Inclusion Criteria:

• Outpatient, male and female 18 to 60 yrs old
• PTSD diagnostic according to DSM-IV criteria
• Patients who agree to receive diagnostic after SCID I application by a trained psychiatrist
• Sexually active female patients who agree to use contraceptive
• Patients who agree to sign the IRB approved informed consent

Exclusion Criteria:

• Patients who have schizophrenic disorder, delusional, psychotic depression, schizo-affective, bipolar and dependence to psychoactive substance disorders
• Patients who have clinical disorders not compensated, which require clinical treatment as priority
• Pregnancy
• Previous renal calculosis history
• Being under antidepressant, or other psychotropic medications
• BMI under 20.

Contacts and Locations

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Investigators
Principal Investigator: Marcelo F Mello, MD UNIFESP

More Information

Responsible Party: UNIFESP (Marcelo Fejo de Mello)
Study ID Numbers: FAPESPTopiramatePTSD
Health Authority: Brazil: National Committee of Ethics in Research