Post Traumatic Stress Disorder and Neural Mechanisms Involved in Its Treatment

Purpose

The post traumatic stress disorder PTSD arises when the physiological response to stress does not come to its term. This study aims to explore the cognitive, psycho physiological and cerebral mechanisms involved in PTSD, in fear conditioning and face matching tasks, before and after treatment. PTSD patients will be recruited by Pr Jean-Claude Samuelian in his service at the Conception Hospital and by Pr Jean-Michel Azorin in his service at the Sainte Marguerite Hospital (Marseille) and will undergo either CBT or EMDR within those same services. The tasks they will be asked to perform will study the psycho physiological, cognitive and central mechanisms involved in PTSD and its treatment. All in all, 17 healthy controls will be recruited as well as 17 PTSD patients for each of the two treatment groups. In terms of perspectives, this study would help isolate neural systems functionally involved in PTSD and its treatment. A better knowledge of those mechanisms would set room for the optimization of the current PTSD treatment.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post Traumatic Stress Disorders</td>
<td>Other: resonance magnetic imaging (fMRI),</td>
</tr>
</tbody>
</table>

Study Type: Interventional  
Study Design: Allocation: Non-Randomized  
Intervention Model: Parallel Assignment  
Masking: Open Label  
Primary Purpose: Basic Science

Official Title: Post Traumatic Stress Disorder and Neural Mechanisms Involved in Its Treatment

Resource links provided by NLM:

MedlinePlus related topics: Post-Traumatic Stress Disorder

U.S. FDA Resources

Further study details as provided by Assistance Publique Hopitaux De Marseille:

Primary Outcome Measures:
- To verify the hypothesis of a levying of inhibition of the CPFm on the tonsil, in the PTSD [ Time Frame: 3 years ] [ Designated as safety issue: No ]

Secondary Outcome Measures:
- Studies of the peripheral, cognitive and central mechanisms, before, then 1 week and 6 months after treatment by CBT or EMDR [ Time Frame: 3 years ] [ Designated as safety issue: No ]

Enrollment: 62  
Study Start Date: April 2009  
Primary Completion Date: May 2012 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Comparator: Healthy volunteers</td>
<td>Other: resonance magnetic imaging (fMRI),</td>
</tr>
</tbody>
</table>
Healthy volunteers without treatment

Experimental: CBT
Psychotraumatized patients treated by Cognitive and Behavioral Therapies (CBT)

Other: resonance magnetic imaging (fMRI), a cerebral study will be performed at the neuroanatomic and functional levels by resonance magnetic imaging (fMRI) realized in three times (before, one week and six months after treatment)

Experimental: EMDR
Psychotraumatized patients treated by Eye Movement Desensitization and Reprocessing (EMDR)

Other: resonance magnetic imaging (fMRI), a cerebral study will be performed at the neuroanatomic and functional levels by resonance magnetic imaging (fMRI) realized in three times (before, one week and six months after treatment)

Eligibility

Ages Eligible for Study: 18 Years to 50 Years (Adult)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:
- French speakers
- Not hospitalized grown-up patients suffering from a post-traumatic stress disorder (PTSD) connected to one event.
- Subjects Controls: grown-up, mated with the patients in age (18 - 50 years; 4 years maximum of difference of age between a patient and his control), in sex and educational level (schooling of the 3rd level, at the level Bac+8; 3 years maximum of difference of educational level between a patient and his control)

Exclusion Criteria:
- Pregnancy
- Feeding
- Nobody under guardianship and grown-up persons being the object of a legal protective measure or not able to express their assent
- Alcoholic or addicted to drugs (including medicines)
- Other neurological disorders or psychiatric that post-traumatic stress disorder (for patients)
- Claustrophobia and contraindications in the IRMf
- Subjects controls, no known psychiatric or neurological pathology, as well as no psychiatric history.
- Persons private of freedom by a court or administrative order, persons hospitalized without assent
- Unability to read French

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: NCT00893568

Locations

France
- Assistance Publique-Hopitaux de Marseille
  Marseille, France

Sponsors and Collaborators
- Assistance Publique Hopitaux De Marseille

More Information

Responsible Party: Assistance Publique Hopitaux De Marseille
ClinicalTrials.gov Identifier: NCT00893568  History of Changes
Other Study ID Numbers: 2009/01  2009-A00193-54
Study First Received: May 5, 2009
Last Updated: August 27, 2014
Health Authority: France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)

Keywords provided by Assistance Publique Hopitaux De Marseille:
- Post traumatic stress disorder PTSD
Additional relevant MeSH terms:
Disease
Stress Disorders, Traumatic
Stress Disorders, Post-Traumatic
Pathologic Processes
Trauma and Stressor Related Disorders
Mental Disorders

ClinicalTrials.gov processed this record on August 16, 2016