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A Eye Movement Desensitization Reprocessing (EMDR) Study in Bipolar Traumatized Patients (BET)

This study has been completed.

Sponsor:
FIDMAG Germanes Hospitalàries

Information provided by (Responsible Party):
Benedikt Amann, FIDMAG Germanes Hospitalàries

ClinicalTrials.gov Identifier:
NCT01620866

First received: June 11, 2012
Last updated: June 18, 2012
Last verified: June 2012
History of Changes

Purpose

The purpose of this pilot study is whether **Eye Movement Desensitization Reprocessing** (**EMDR**), an approved psychotherapy in posttraumatic stress disorder, improves mood, functioning, quality of life, cognition and BDNF levels in subsyndromal bipolar patients with trauma.

Condition	Intervention
Bipolar Disorder PTSD	Other: **Eye Movement Desensitization Reprocessing** (**EMDR**)

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Controlled, Single-blind Pilot Study of **EMDR** in Bipolar, Subsyndromal Patients With Trauma

Resource links provided by NLM:

MedlinePlus related topics: Bipolar Disorder Wounds and Injuries

U.S. FDA Resources

Further study details as provided by FIDMAG Germanes Hospitalàries:

Primary Outcome Measures:

- The primary outcome of this study is a statistically significant reduction in the YMRS and/or HDRS in the **EMDR** group compared with the TAU group. [Time Frame: 3 months and 6 months] [Designated as safety issue: No]

  Patients with subsydromal symptoms, objectified by the YMRS and HDRS, are included in the study. After randomization to EMDR or TAU, group differences in changes in the YMRS and HRDS are measured at visit after intervention (3 months) and at follow-up (6 months). The hypothesize is that the EMDR group will statistically improve in both affective scales when compared to the TAU group.

Secondary Outcome Measures:

- The **EMDR** group improves statistically significant in trauma load when compared to TAU. [Time Frame: 3 months and 6 months] [Designated as safety issue: No]

  Secondary outcome measure includes changes in trauma scales (IES, CAPS)from baseline to 3 months and 6 months.

- The **EMDR** group improves statistically significant in cognitive tests when compared to TAU. [Time Frame: 3 months and 6 months] [Designated as safety issue: No]

  Subjects underwent a neuropsychologcial battery to test various cognitive domains.

- The **EMDR** group improves statistically significant in functioning when compared to TAU. [Time Frame: 3 months and 6 months]
  [Designated as safety issue: No]

  All subjects were evaluated with respect to their functioning using the FAST, a validated scale of functioning in bipolar disorder.

- The **EMDR** group improves statistically significant in quality of life when compared to TAU. [Time Frame: 3 months and 6 months]
  [Designated as safety issue: No]

  Possible changes of Quality of life were tested in all subjects as well, using the SF-36.

- Plasma levels of BDNF was statistically higher in the **EMDR** group after intervention when compared to TAU. [Time Frame: 3 months and 6 months]
  [Designated as safety issue: No]

  Levels of BDNF are lower in bipolar patients, and even lower when traumatized, when compared to the general population. We aimed to find higher levels of BDNF in the EMDR group.

Enrollment: 20
Study Start Date: November 2010
Study Completion Date: June 2012
Primary Completion Date: June 2012 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: **EMDR**	Other: **Eye Movement Desensitization Reprocessing** (**EMDR**) **EMDR** is an effective treatment in PTSD but has never been tested in bipolar traumatized patients.
No Intervention: TAU Treatment as usual (TAU)	

Eligibility

Ages Eligible for Study: 18 Years to 65 Years (Adult)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Bipolar I or II disorder following DSM-IV criteria
- Instable, subsyndromal course defined as at evaluation baseline (HAMD > 8 < 15 and/or YMRS > 7 < 14)
- Good adherence to pharmacological treatment
- Major or minor traumatic life-events
- EMDR therapists > 3 years experience
- Able to sign informed consent

Exclusion Criteria:

- Major affective episode in last 3 months
- Active drug abuse/dependency
- Neurological disease
- Suicidal thoughts/ideation
- Prior treatment EMDR
- DES > 25

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: NCT01620866

Locations

Spain

FIDMAG

Barcelona, Spain, 08035

Sponsors and Collaborators

FIDMAG Germanes Hospitalàries

Investigators

Principal Investigator: Benedikt L Amann, MD FIDMAG Germanes Hospitalàries

More Information

Publications:

Kauer-Sant'Anna M, Tramontina J, Andreazza AC, Cereser K, da Costa S, Santin A, Yatham LN, Kapczinski F. Traumatic life events in bipolar disorder: impact on BDNF levels and psychopathology. Bipolar Disord. 2007 Jun;9 Suppl 1:128-35.

Bisson J, Andrew M. Psychological treatment of post-traumatic stress disorder (PTSD). Cochrane Database Syst Rev. 2007 Jul 18;(3):CD003388. Review. Update in: Cochrane Database Syst Rev. 2013;12:CD003388.

Responsible Party:	Benedikt Amann, Senior researcher, FIDMAG Germanes Hospitalàries
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Keywords provided by FIDMAG Germanes Hospitalàries:
EMDR
bipolar disorder
trauma
subsyndromal symptoms
PTSD

Additional relevant MeSH terms:
Bipolar Disorder
Bipolar and Related Disorders
Mental Disorders

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