https://clinicaltrials.gov/ct2/show/NCT01605253?term=Eszopiclone&cond=PTSD&draw=2&rank=1

Clinical trial registration statement: The study was registered on ClinicalTrials.gov. The registration identification number is NCT01605253.

Eszopiclone for the Treatment of Posttraumatic Stress Disorder

ClinicalTrials.gov Identifier: NCT01605253

Recruitment Status : Completed
First Posted : May 24, 2012
Last Update Posted : April 15, 2016

Sponsor:
Rush University Medical Center

Collaborator:
National Institute of Mental Health (NIMH)

Information provided by (Responsible Party):
Rush University Medical Center

Study Details | Tabular View | Results Submitted | Disclaimer

How to Read a Study Record

Study Description

Go to

Brief Summary:

The purpose of this study is to determine if **eszopiclone** relative to placebo (sugar pill) is effective and tolerable for people with posttraumatic stress disorder (PTSD)-related sleep disturbance. The investigators will also examine the impact of treatment on sleep patterns, memory recall bias, and level of inflammatory markers (cytokines). The investigators predict **eszopiclone** will lead to greater improvement than placebo in measures of PTSD symptoms, memory recall bias, and level of inflammatory markers.

Condition or disease	Intervention/treatment	Phase
Posttraumatic Stress Disorders	Drug: **Eszopiclone** Drug: Placebo	Phase 4

Study Design

Go to

Study Type:	Interventional (Clinical Trial)
Actual Enrollment:	81 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Double (Participant, Investigator)
Primary Purpose:	Treatment
Official Title:	**Eszopiclone** for the Treatment of **PTSD**
Study Start Date:	March 2012
Actual Primary Completion Date:	December 2015
Actual Study Completion Date:	December 2015

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Post-Traumatic Stress Disorder

Drug Information available for: Eszopiclone

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Active Comparator: **Eszopiclone** The total study duration is 16 weeks, with subjects taking 3mg **eszopiclone** at bedtime for 12 weeks. There is one follow-up visit after the 12 week treatment phase.	Drug: **Eszopiclone** **Eszopiclone** has been approved by the US Food and Drug Administration (FDA) for the treatment of insomnia (inability to sleep). **Eszopiclone** has not been specifically approved by the FDA for people who have PTSD-related sleep disturbance. Other Name: **Lunesta®**
Placebo Comparator: Placebo The total study duration is 16 weeks, with subjects taking placebo at bedtime for 12 weeks. There is one follow-up visit after the 12 week treatment phase.	Drug: Placebo The placebo used in this study looks exactly like **eszopiclone** but contains no active ingredients.

Outcome Measures

Go to

Primary Outcome Measures :

1. Symptoms of Posttraumatic Stress Disorder [Time Frame: 16 weeks]

Secondary Outcome Measures :

1. Sleep disturbance [Time Frame: 16 weeks]

   Total sleep time, sleep latency, and number of awakenings.

2. Memory recall bias [Time Frame: Baseline and week 12 (pre and post treatment)]
3. Inflammatory markers (cytokines) [Time Frame: Baseline and week 12 (pre and post treatment)]

Eligibility Criteria

Go to

Information from the National Library of Medicine NIH NLM

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:	18 Years to 65 Years (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Male or female outpatients age 18-65 with a primary diagnosis of PTSD and associated sleep disturbance
- Good physical health
- Willingness and ability to comply with the requirements of the study protocol

Exclusion Criteria:

- Women pregnant, lactating, or of childbearing potential not using medically accepted contraception
- Concurrent use of other psychotropic medications at least two weeks prior to baseline
- Concurrent use of other anti-inflammatory medications or anti-cytokine medications. If used on an as-needed (PRN) basis, subjects may enter the study, but will be excluded from cytokine analyses
- Concurrent use of beta-blockers less than one month prior to baseline
- Serious medical illness or instability for which hospitalization may be likely within the next year
- Seizure disorders with the exception of a history of febrile seizures if they occurred during childhood
- Sleep apnea or restless leg syndrome

- Concurrent psychotherapy initiated within 3 months of randomization or ongoing psychotherapy of any duration directed specifically toward treatment of PTSD and/or sleep disturbance
- Patients with significant suicidal ideation
- Current legal actions related to trauma or an ongoing relationship with assailant

Contacts and Locations

Go to

Information from the National Library of Medicine NIH NLM

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): **NCT01605253***

Locations

United States, Illinois

Center for Anxiety and Traumatic Stress Disorders at Rush
Chicago, Illinois, United States, 60612

Sponsors and Collaborators

Rush University Medical Center

National Institute of Mental Health (NIMH)

Investigators

Principal Investigator: Mark Pollack, MD Rush University Medical Center

More Information

Go to

Responsible Party: Rush University Medical Center
ClinicalTrials.gov Identifier: NCT01605253 History of Changes

Other Study ID Numbers:	1R34MH091338-01A1 (U.S. NIH Grant/Contract)
	1R34MH091338-01A1 (U.S. NIH Grant/Contract)
First Posted:	May 24, 2012 Key Record Dates
Last Update Posted:	April 15, 2016
Last Verified:	May 2015

Keywords provided by Rush University Medical Center:

Post-traumatic stress disorder	anxiety
sleep disturbance	traumatic event
insomnia	memory
cytokines	

Additional relevant MeSH terms:

Stress Disorders, Traumatic	**Eszopiclone**
Stress Disorders, Post-Traumatic	Hypnotics and Sedatives
Trauma and Stressor Related Disorders	Central Nervous System Depressants
Mental Disorders	Physiological Effects of Drugs