

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effectiveness of Prazosin for sleep problems of patients with post-stress traumatic disorder -chronic, war type

Protocol summary

Summary

This project is a quasi-experimental design with one group with pretest-posttest. It is aimed at evaluating the effectiveness of Prazosin in reducing sleep problems in patients with post-stress traumatic disorder. 32 participants are selected among patients with post-stress traumatic disorder, which have sleep problems, according to clinical interview using DSM-IV-TR. They are evaluated with a demographic questionnaire, medical history, the structured interview of CAPS-1, and PCL questionnaire. Their sleep quality and quantity are assessed using Pittsburg sleep quality and Actigraph. The patients take Prazosin in addition to their previous medications. 1 ml g Prazosin is taken 1 hour before sleep, for 3 nights, then 2 ml g for 4 nights. If patient's nightmares were not reduced and there was no side effect, it will be increased to 2 ml g per week, until 10 ml g. If the problem persists, it will be also increased until 15 ml g per week. Then, all the participants will be evaluated according to all the pretests.

General information

Acronym

PTSD

IRCT registration information

IRCT registration number: **IRCT2013022512596N1**

Registration date: **2013-05-07, 1392/02/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-07, 1392/02/17

Registrant information

Name

Habiballah Khazaie

Name of organization / entity

Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Kermanshah University of Medical Sciences and Health Services

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of Prazosin for sleep problems of patients with post-stress traumatic disorder -chronic, war type

Public title

The effects of Prazosin in treating sleep problems of patients with post-stress traumatic disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients subject to post-stress traumatic disorder chronic war type according to DSM-IV-TR in a clinical interview by a psychiatrist, with sleep problems; Duration of the disorder is more than 6 months; participants' age is between 18 and 60 years

(minimum of 18 years as a criterion of adulthood, and 60 years for the practicability of test taking). Exclusion criteria: history of mania, schizophrenia and other psychotic disorders; depression with suicide ideas; orthostatic hypotension and medicine sensitivity.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research of Kermanshah University of Medical Sciences and Health Services

Street address

Shahid Beheshti boulevard

City

Kermanshah

Postal code

Approval date

2013-01-16, 1391/10/27

Ethics committee reference number

48649

Health conditions studied

1

Description of health condition studied

sleep problems

ICD-10 code

F51.5

ICD-10 code description

nightmares

2

Description of health condition studied

post traumatic stress disorder

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder

3

Description of health condition studied

sleep problems

ICD-10 code

F51.4

ICD-10 code description

sleep terrors

4

Description of health condition studied

sleep problems

ICD-10 code

G47.0

ICD-10 code description

Disorders of initiating and maintaining sleep [insomnias]

Primary outcomes

1

Description

PTST intensity

Timepoint

the start of the study, two months after the medication started

Method of measurement

the structured interview of CAPS-1

2

Description

sleep problems

Timepoint

the start of the study, two months after the medication started

Method of measurement

the structured interview of CAPS-1, PCL questionnaire, Actigraph

Secondary outcomes

empty

Intervention groups

1

Description

Prazosin prescription: 1 mg 1 hour before sleep for 3 nights, then it increases up to 2 mg for seven nights. In the case of ineffectiveness and lack of counter-indications, the medication increases 2 mg per week

until 10 mg, before sleep. The consumption is fixed if the patient report any sign of effectiveness; unless, it increases up to 15 mg per night, in the case of lack of counter-indication.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi hospital

Full name of responsible person

Marzie Nasuri

Street address

Farabi Hospital

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Farabi hospital, Kermanshah university of medical science

Street address

Shahid Beheshti boulevard

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Kermanshah University of Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah university of medical science

Full name of responsible person

Dr. Habiballah Khazaie

Position

National board of psychiatry

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty