Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study of efficacy of prazocin on patient with post traumatic stress disorder

Protocol summary

Summary

One of the most common disorder of patients who experience post traumatic stress disorder is sleep disorders such as night mare and insomnia. In this study we are going to know if prazocine has any efficacy on sleep disorder of patients who experince post traumatic stress disorder. Participants will be 100 male and female who are under 45 years old, without cardiac disease and substances abuse. they will be grouped randomly in three treatment groups for during 8-10 weeks: 1- first will take prazocine, second will take hydrocizine and last one will take placebo. Results will be compared according to Pittursburgs Sleep Quality Index before and after the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012085341N1**
Registration date: **2011-04-13, 1390/01/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-04-13, 1390/01/24

Registrant information

Name

Parastou Sabzehee

Name of organization / entity

Hamadan university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research center for behavioral disorders and substances abuse, Hamadan

Expected recruitment start date

2011-01-05, 1389/10/15

Expected recruitment end date

2011-12-05, 1390/09/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of efficacy of prazocin on patient with post traumatic stress disorder

Public title

Study of efficacy of prazocin on patient with post traumatic stress disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients who have post traumatic stress disorder, age under 45 year, absence of heart disease, not having history of substances abuses.
Exclusion criteria: hypotension during treatment.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan university of medical sciences
Street address
Hamadan university of medical sciences
City
Hamadan
Postal code
Approval date
2011-01-22, 1389/11/02
Ethics committee reference number
16/35/9/163573/پ

Health conditions studied

1

Description of health condition studied
Post traumatic stress disorder
ICD-10 code
F43.1
ICD-10 code description
Post-traumatic stress disorder

Primary outcomes

1

Description
sleep disorders
Timepoint
with 3 months interval
Method of measurement
Pittursburgs Sleep Quality Index

Secondary outcomes

1

Description
sleep enhancement
Timepoint
with 3 months interval
Method of measurement
Pittursburgs Sleep Quality Index

Intervention groups

1

Description
first group: prazosine 1-5 mg for 8 weeks
Category
Treatment - Drugs

2

Description
second group: hydrocizine 10-100 mg for 8 weeks
Category
Treatment - Drugs

3

Description
third group: placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Psychiatrists
Street address
Pastor cross road
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamadan University of Medical Sciences
Full name of responsible person
Dr. Ghaliha
Street address
Vice Chancellor for Research, Hamadan University of Medical Sciences
City
Hamadan
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamadan University of Medical Sciences
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
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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