

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Investigation effects of Tamsulosin on disturbing dreams and nightmares: a cross over pilot study

Protocol summary

Summary

Nightmare disorder is a parasomnia that affects around 4% of population. It can impair quality of life and sleep, predispose to insomnia, daytime sleepiness and fatigue. Based on DSM-IV definition nightmares are extremely frightening dreams that awakes the sleeper with a detailed memory and a quick orientation afterwards. Trauma nightmares are one of the important characterizations of Post-traumatic stress disorder. Several studies shows prazosin efficacy on reduction of these nightmares and significant sleep improvement by decreasing adrenergic tone in CNS. Therefore we decided to investigate effects of tamsulosin in a double-blind placebo controlled clinical trial on nightmares (and not only those are PTSD but also every patient who have sever nightmares) which have a better pharmacokinetic versus prazosin. 20 patients suffering from nightmare disorder and fulfill inclusion criteria are targeted by scoring disturbing dreams and nightmares severity index (DDNSI) questionnaire for 10week assessment following: 4week tamsulosin or placebo 2week wash out(neither tamsulosin nor placebo) 4week tamsulosin or placebo. Patients At week 0(baseline), weeks 4, 6, 10 will have an appointment to assess by DDNSI and ask about sleep improvement or any side effect. Inclusion criteria: patients who have nightmare disorder and get necessary score on mentioned index and have complains about nightmares and would get benefit from therapy. Exclusion criteria: patients who have a low blood pressure, sensitivity to tamsulosin, occurrence of serious side effect. We expect tamsulosin versus placebo shows a great reduction on DDNSI which means disturbing dreams and nightmares decreases by tamsulosin and probably would have beneficial effect for who have nightmare disorder.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412163106N21**

Registration date: **2015-01-14, 1393/10/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-14, 1393/10/24

Registrant information

Name

Farshad Hashemian

Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

Country

Iran (Islamic Republic of)

Phone

+98 21 2260 0037

Email address

hashemian.f@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Pharmaceutical sciences branch of Islamic Azad university

Expected recruitment start date

2014-12-06, 1393/09/15

Expected recruitment end date

2015-03-11, 1393/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation effects of Tamsulosin on disturbing dreams and nightmares: a cross over pilot study

2014-08-20, 1393/05/29

Ethics committee reference number
6125

Public title

Effect of tamsulosin on nightmares

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Nightmare disorder Patients who are interested in treatment and earn necessary score on disturbing dreams and nightmares severity index (DDNSI) questionnaire; 2. No concomitant disease that limit the use of tamsulosin; 3. Quality of life and sleep impairment make drug therapy beneficial; 4. No concomitant drug therapy which have life threatening interactions with tamsulosin Exclusion criteria: 1. Patients who have a low blood pressure occurrence serious side effect; 2. Patients who are not interested for treatment; 3. Patients who have sensitivity to sulfa drugs and tamsulosin or ingredients; 4. Occurrence of serious side effect like severe orthostatic hypotension; 5. Patients with cardiovascular disease.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Pharmaceutical science branch of Islamic Azad University

Street address

No.99, Yakhchal street, Dr. Shariati Avenue

City

Tehran

Postal code

Approval date

Health conditions studied

1

Description of health condition studied

Nightmare disorder

ICD-10 code

F51.5

ICD-10 code description

Nightmares

Primary outcomes

1

Description

Reduction or totally disappearing disturbing dreams and nightmares

Timepoint

Weeks: 0, 4, 6 and 10

Method of measurement

Disturbing dreams and nightmares severity index questionnaire and interviewing about sleep improvement

Secondary outcomes

1

Description

Reported side effectd-hypotension

Timepoint

Weeks: 0, 4, 6 and 10

Method of measurement

Blood pressure monitoring

Intervention groups

1

Description

This study is designed crossover so the following will be done: 4 weeks tamsulosin or placebo 0.4mg capsule every night; 2 weeks wash out (neither tamsulosin nor placebo) then 4 weeks placebo or tamsulosin 0.4mg capsule every night. Patients are instructed to take the drug at least half an hour after dinner with a glass of water.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pharmaceutical science branch of Islamic Azad

university

Full name of responsible person

Negin Naderifar

Street address

No.99, Yakhchal street, Dr. Shariati Avenue

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic azad university of pharmaceutical science

Full name of responsible person

Dr. Sepideh Arbabi Bigdeli

Street address

No.99, Yakhchal street, Dr. Shariati Avenue Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic azad university of pharmaceutical science

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Pharmaceutical science branch of Islamic Azad university

Full name of responsible person

Dr. Farshad Hashemian

Position

Associate Professor

Other areas of specialty/work

Street address

No.99, Yakhchal street, Dr. Shariati Avenue

City

Tehran

Postal code

Phone

+98 21 2264 0056

Fax

Email

hashemian.f@iaups.ac.ir

Web page address

Person responsible for updating data

Contact

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