Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 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. Therefor 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

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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

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 cardiovascolar 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
2014-08-20, 1393/05/29
Ethics committee reference number
6125

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic azad university of pharmaceutical sciense

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 sciense

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

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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