Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing effect of tizanidine hydrochloride vs. placebo on muscle cramp in hemodialysis patients in

Protocol summary

Summary

This study is designed to investigate the effect of tizanidine compared with placebo on muscle cramps in hemodialysis patients. All patients participating in this study are from three hemodialysis centers in Isfahan and one hemodialysis center in Shahrekord. All patients will enroll who are at least 18 year old and at least 3 months on two or three times weekly hemodialysis and experienced at least once weekly muscle cramp without hypotension during the last month. Methods, benefits and side effects of tizanidine are described to the patients, and their written informed consents are obtained. This study is a double-blind, crossover, census, and phase 3 clinical trial. All patients are randomly allocated into A or B groups, and receive either 2mg tizanidine hydrochloride or placebo one hour before each hemodialysis session. Patients in group A at first receive tizanidine for one month and after 3 days washout period, receive placebo for one month. In contrast patients in group B receive first placebo and then tizanidine. Necessary laboratory tests are obtained before each study phase. The patients' vital signs are measured and recorded before prescribing medication, and at the start of each hemodialysis session, then every hour until the end of hemodialysis session and at the start of each muscle cramp episode by responsible hemodialysis nurse. In each hemodialysis session responsible hemodialysis nurse determines and records the duration, intensity and the number of muscle cramps. Severity of muscle cramps is measured by visual analog scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510251598N3**
Registration date: **2016-02-16, 1394/11/27**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-02-16, 1394/11/27

Registrant information

Name
Shahram Taheri
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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+98 31 3625 5555
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sh_taheri@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences.

Expected recruitment start date

2010-03-20, 1388/12/29

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of tizanidine hydrochloride vs. placebo on muscle cramp in hemodialysis patients in

Public title

Comparing effect of tizanidine hydrochloride vs. placebo on muscle cramp in hemodialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: At least 18 year old; give informed consent to participate in the 2 month clinical trial; at least has once weekly muscle cramp episode during previous month; stable hemodialysis patients and no hypotension during muscle cramp episode (Systolic BP≥90 mmHg); chronic hemodialysis patients for at least 3 months; serum calcium level≥ 8.3 mg/dL; serum sodium level≥ 135 mEq/L Exclusion criteria: side effect appearing to tizanidine; any time patient wishes to exit from the study.

Age
From **18 years** old to **99 years** old

Gender
Both

Phase
3

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
Medical research ethics committee at the Isfahan University of Medical Sciences

Street address
Research vice president of Isfahan University of Medical Sciences , Building 4, Hezar Jerib St.

City
Isfahan

Postal code

Approval date
2009-11-03, 1388/08/12

Ethics committee reference number
پ/12/40/81318

Health conditions studied

1

Description of health condition studied
muscle cramp in hemodialysis patients

ICD-10 code
R25.2,Z49.

ICD-10 code description
Cramp and spasm,Extracorporeal dialysis

Primary outcomes

1

Description
Muscle cramp frequency

Timepoint
During hemodialysis session

Method of measurement
Observation by responsible hemodialysis nurse

2

Description
Muscle cramp intensity

Timepoint
During hemodialysis session

Method of measurement
Visual analog scale

3

Description
Muscle cramp duration (second)

Timepoint
During hemodialysis session

Method of measurement
Measuring by responsible nurse

Secondary outcomes

1

Description
Systolic and diastolic blood pressure

Timepoint
At the time of tizanidine hydrochloride or placebo prescription and then at the start of hemodialysis session and hourly during hemodialysis and at the start of each muscle cramp episode

Method of measurement
Sphigmomanometer by responsible nurse

2

Description
Pulse rate (beats per minute)

Timepoint
At the time of tizanidine hydrochloride or placebo prescription and then at the start of hemodialysis session and hourly during hemodialysis and at the start of each muscle cramp episode

Method of measurement
watch, by responsible nurse

Intervention groups

1

Description
Group A at first receives tizanidine hydrochloride for one month and after 3 days washout period receives placebo for another month. Serum Na, K, calcium, phosphate, albumin, and complete blood cell count are measured before each phase of study. Patients' systolic and diastolic blood pressure and pulse rate are monitored at the time of drug or placebo administration and at the start of each hemodialysis session and then hourly till the end of hemodialysis and at the start of each muscle cramp episode. The number of muscle cramps in each hemodialysis session are recorded by responsible hemodialysis nurse. At the start of each muscle cramp episode duration and intensity of muscle cramp is measured by corresponding hemodialysis nurse. Intensity of muscle cramp is measured by visual analog scale from zero to ten specified by patients on the questionnaire. After starting muscle cramp the patients will be treated by hypertonic saline to abort the muscle cramp.

Category
Prevention

2

Description
Group B at first receives placebo for one month and after 3 days washout period receives tizanidine hydrochloride for another month. Serum Na, K, calcium, phosphate, albumin, and complete blood cell count are measured before each phase of study. Patients' systolic and diastolic blood pressure and pulse rate are monitored at the time of drug or placebo administration and at the start of each hemodialysis session and then hourly till the end of hemodialysis and at the start of each muscle cramp episode. The number of muscle cramps in each hemodialysis session are recorded by responsible hemodialysis nurse. At the start of each muscle cramp episode duration and intensity of muscle cramp is measured by corresponding hemodialysis nurse. Intensity of muscle cramp is measured by visual analog scale from zero to ten specified by patients on the questionnaire. After starting muscle cramp the patients will be treated by hypertonic saline to abort the muscle cramp.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Hemodialysis Center, Amin Hospital
Full name of responsible person
Dr. Shahram Taheri
Street address
Ebne Sina St., Shohada Sq.
City
Isfahan

2

Recruitment center
Name of recruitment center
Hemodialysis Center, Zahra Marzieh Hospital
Full name of responsible person
Dr. Shahram Taheri
Street address
Alameh Majlesi St., Qods Sq.
City
Isfahan

3

Recruitment center
Name of recruitment center
Hemodialysis Center, Shariati Hospital
Full name of responsible person
Dr. Mahboobeh Bemanian
Street address
Dr. Shariati St.
City
Isfahan

4

Recruitment center
Name of recruitment center
Hemodialysis Center, Hajar Hospital
Full name of responsible person
Dr. Ali Momeni
Street address
Parastar St.
City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan Kidney Diseases Research Center, Isfahan University of Medical Sciences
Full name of responsible person
Dr. Mojgan Mortazavi
Street address
Isfahan Kidney Diseases Research Center, Alzahra Hospital, Soffeh Ave..
City
Isfahan
Grant name
Grant code / Reference number
288155
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan Kidney Diseases Research Center, Isfahan

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

Name of organization / entity

Isfahan Kidney Diseases Research Center, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Shahram Taheri

Position

Adult nephrologist, associate professor

Other areas of specialty/work

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Associate professor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Adult nephrologist, associate professor

Other areas of specialty/work

Street address

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City

Isfahan

Postal code

Phone

+98 31 3625 5555

Fax

Email

sh_taheri@med.mui.ac.ir, shah63tah@yahoo.com

Web page address

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