

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Country

Iran (Islamic Republic of)

Phone

+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 \geq 90 mmHg); chronic hemodialysis patients for at least 3 months; serum calcium level \geq 8.3 mg/dL; serum sodium level \geq 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

12/40/81318/ب

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
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Full name of responsible person
Dr. Shahram Taheri
Position
Adult nephrologist, associate professor
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Fax
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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