

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of pentoxifylline on reducing incidence of restless leg syndrome in patients undergoing hemodialysis

Protocol summary

Study aim

Determine the effect of pentoxifyllin on reducing the incidence of restless leg syndrome

Design

clinical trial with 2 different group and blinded by delivering the encrypted cards to the patients by secretary

Settings and conduct

This study is contains 2 different group of patients that blinded by delivering the encrypted cards to the patients by secretary .

Participants/Inclusion and exclusion criteria

All the patients that undergoing dialysis that give informed consent

Intervention groups

20 patients that undergoing dialysis treated with pentoxifylline and 20 with placebo

Main outcome variables

Pain and leg comfort

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180219038797N1**

Registration date: **2018-04-20, 1397/01/31**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-20, 1397/01/31**

Update count: **0**

Registration date

2018-04-20, 1397/01/31

Registrant information

Name

Reza Saberirad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3881 1341

Email address

rsaberirad@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2018-06-05, 1397/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pentoxifylline on reducing incidence of restless leg syndrome in patients undergoing hemodialysis

Public title

Effect of pentoxifylline on restless leg syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All the patients undergoing hemodialysis that have Informed consent

Exclusion criteria:

Patient dissatisfaction Death

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Delivery of encrypted cards by secretary to patients

Blinding (investigator's opinion)

Triple blinded

Blinding description

Delivering the encrypted cards to the patients by secretary

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Tawhid settlement , University compound of Sabzevar University of Medical Sciences

City

Mashhad

Province

Razavi Khorasan

Postal code

9613873136

Approval date

2018-02-19, 1396/11/30

Ethics committee reference number

IR.MEDSAB.REC.1396.138

Health conditions studied

1

Description of health condition studied

Restless Leg Syndrome

ICD-10 code

G25.81

ICD-10 code description

Restless legs syndrome

Primary outcomes

1

Description

Pain and comfort of legs

Timepoint

At the end of each month for 3 months

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: prescription of 1 pentoxifylline tablet (400 mg) daily for 3 months

Category

Treatment - Drugs

2

Description

Control group: prescription of 1 placebo daily for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vaseei Hospital

Full name of responsible person

Zahra Mirhoseini

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Touhid shahr Blvd , Sabzevar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sabzevar University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Reza Saberi Rad

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific**inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data, including a questionnaire, can be shared.

When the data will become available and for how long

3 months after the results

To whom data/document is available

University researchers

Under which criteria data/document could be used

Researchers in the field

From where data/document is obtainable

Zahra Mirhoseini Vase`ee Hospital Sabzevar

00989155081275 zahra_mir2002@yahoo.com

What processes are involved for a request to access data/document

The researchers submit their application via email.

Comments