Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

pramipexole vs. placebo for patients with restless leg syndrome associated chronic renal failure undergoing dialysis

Protocol summary

Summary

The purpose of this study is effect of pramipexole on patients with restless leg syndrome(RLS) an end stage renal disease(ESRD).In this double-blind randomized clinical trial,twenty patients with ESRD undergoing dialysis in martyr Mostafa Khomeini hospital in Ilam between January to March in 1392 are enrolled. Patients who older than 18 years and more 12 weeks of dialysis are included. Patients with Iron and folate-deficiency and younger than 18 years and less than 12 week of dialysis are excluded. Patients will screen by Standard questionnaires for the diagnosis of RLS by the interviewer. The intensity and frequency of RLS symptoms with RLS Rating Scale questionnaire is determined by the interviewer. The patients were divided into two groups.The patients were Pramipexole 0.045 mg or placebo for one month will be given daily.The intensity and frequency of RLS symptoms with RLS Rating Scale questionnaire is determined again by the interviewer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014011216183N1**
Registration date: **2014-04-14, 1393/01/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-14, 1393/01/25

Registrant information

Name

Sadegh Ehsanbakhsh

Name of organization / entity

Ilam University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 84 1223 5700

Email address

sadegh.ehsanbakhsh@gmail.com

Recruitment status

Recruitment complete

Funding source

Ilam University of Medical Sciences

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

pramipexole vs. placebo for patients with restless leg syndrome associated chronic renal failure undergoing dialysis

Public title

treatment of Restless Leg Syndrome associated end stage renal disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with End Stage Renal Disease (ESRD); older than 18 years; more 12 week undergoing dialysis; patients with Restless Leg Syndrome (RLS)
Exclusion criteria: patients with iron and folate deficiency

Age

From **18 years** old to **90 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
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ilam University of Medical Sciences
Street address
Banganjab, medical faculty, Ilam, Iran
City
Ilam
Postal code
6456134641
Approval date
2014-03-08, 1392/12/17
Ethics committee reference number
EC/92/H/213

Health conditions studied

1

Description of health condition studied
restless leg syndrome, chronic renal failure
ICD-10 code
G25.8
ICD-10 code description
Other specified extrapyramidal and movement disorders

Primary outcomes

1

Description
intensity of symptoms
Timepoint
before and 1 month after intervention
Method of measurement
Standard questionnaires

2

Description
frequency of symptoms
Timepoint
before and 1 month after intervention
Method of measurement
Standard questionnaires

Secondary outcomes

1

Description
side effects
Timepoint
One month after of intervention
Method of measurement
Standard questionnaire

Intervention groups

1

Description
Intervention group: patients will be given a quarter of tablet pramipexole 0.18 mg daily for 1 month
Category
Treatment - Drugs

2

Description
Control group: patinets will be given a quarter of tablet placebo daily for 1 month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis center in Martyr Mostafa Khomeini Hospital in Ilam
Full name of responsible person
Sadegh Ehsanbakhsh
Street address
Dialysis center in Martyr Mostafa Khomeini Hospital in Ilam
City
Ilam

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person

Dr. Taherikalani
Street address
Banganjab,
City
Ilam
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam 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
Ilam University of Medical Sciences
Full name of responsible person
Dr. Rahmatian
Position
professor
Other areas of specialty/work
Street address
Martyr Mostafa Khomeini Hospital
City
Ilam
Postal code
Phone
+98 84 1223 8456
Fax
Email
aryoobarzan.rahmatian@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Dr. Rahmatian
Position
professor
Other areas of specialty/work
Street address
Martyr Mostafa Khomeini Hospital
City
Ilam
Postal code
Phone
+98 84 1223 8456
Fax
Email
aryoobarzan.rahmatian@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Sadegh Ehsanbakhsh
Position
Medical student
Other areas of specialty/work
Street address
Banganjab
City
Ilam
Postal code
Phone
+98 84 1223 5700
Fax
Email
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