

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Effects of physical practice on Quality of life, physical activity & power of judge in hemodialyses patients

Protocol summary

2018-05-31, 1397/03/10

Study aim

Effects of physical practice on Quality of life, physical activity & power of judge in hemodialyses patients

Design

This study is clinical trial and double blind.45 patients undergoing hemodialysis in Valiasr Hospital are enrolled.30 patients in the exercise group and 15 patients in the control group.

Settings and conduct

This study is clinical trial and double blind.45 patients undergoing hemodialysis in Valiasr Hospital are enrolled.The analyzer and outcome reviewer is not aware of the treatment received.this study is double blind.

Participants/Inclusion and exclusion criteria

Effects of physical practice on Quality of life, physical activity & power of judge in hemodialyses patients

Intervention groups

We will divide patients in 2 groups(exercise and control).We is performed exercise 3 times a week according to the schedule of dialysis days, and preferably in the first 2 hours of hemodialysis in intervention group.There is no exercise program in the control group.

Main outcome variables

Quality of life, evaluation of muscle strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N78**

Registration date: **2018-05-31, 1397/03/10**

Registration timing: **retrospective**

Last update: **2018-05-31, 1397/03/10**

Update count: **0**

Registration date

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-11-19, 1393/08/28

Expected recruitment end date

2016-11-18, 1395/08/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of physical practice on Quality of life, physical activity & power of judge in hemodialyses patients

Public title

Effects of physical practice on Quality of life, physical activity & power of judge in hemodialyses patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

18-60 years There is no myocardial infarction in the last 1 month Lack of visual impairment or hearing loss Do not

use drugs that cause cognitive impairment, such as chemotherapy drugs

Exclusion criteria:
A member's amputation is a condition in which the patient is not able to use a fixed bike Perform less than 70% of the exercise program. Uncontrolled diabetes pregnant women CVA recent

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization with use random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Analyzer and outcome reviewer is not aware of the treatment received.this study is double blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij squire, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Approval date

2016-11-18, 1395/08/28

Ethics committee reference number

93-168-1

Health conditions studied

1

Description of health condition studied

Hemodialysis

ICD-10 code

R88.0

ICD-10 code description

Cloudy (hemodialysis) (peritoneal) dialysis effluent

Primary outcomes

1

Description

Quality of life

Timepoint

Before exercise, third and sixth months

Method of measurement

Quality of Life Questionnaire

2

Description

Evaluation of muscle strength

Timepoint

Before the beginning of the exercise program, 12 week and 24 week exercise program

Method of measurement

sports test sit and stand 30 second

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We is performed exercise 3 times a week according to the schedule of dialysis days, and preferably in the first 2 hours of hemodialysis in intervention group.

Category

Treatment - Other

2

Description

Control group: There is no exercise program in the control group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Parvin Soltani

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

soltani.parvin@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Arjmandzadegan

Street address

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

38149578558

Phone

+98 86 3417 3638

Fax

+98 86 3222 2003

Email

arjmandzadegan@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Leila Poursaadat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

38149578558

Phone

+98 86 3417 3638

Email

Porsaadat@arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Parvin Soltani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

38149578558

Phone

+98 86 3417 3638

Email

soltani.parvin@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Parvin Soltani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Payambar azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

38149578558

Phone

+98 86 3222 2003

Email

soltani.parvin@yahoo.com

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

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Parvin Soltani

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

They have to write letters to the professors and the university.

Comments