

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Determining the effect of a wrist exercise program on the maturation of arteriovenous fistula and Steele's syndrome in hemodialysis patients

Protocol summary

Study aim

Determining the effect of a wrist exercise program on the maturation of arteriovenous fistula in hemodialysis patients

Design

A controlled, parallel-group, unblinded, randomized, phase 3 clinical trial on 116 patients. For randomization, the block randomization method using blocks of 4 was used.

Settings and conduct

A randomized clinical trial study that will be conducted on dialysis patients in Arak city. After entering the study, patients will be randomly divided into intervention and control groups. The results will be analyzed after 3 months of intervention. Blinding was not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients who have undergone hemodialysis and have undergone Arteriovenous fistula (AVF) surgery, over 18 years of age, should undergo dialysis at least 2 times a week. Exclusion criteria: suffering from other chronic diseases.

Intervention groups

In the intervention group, 58 patients do an exercise program at home using a CD. Wrist exercises will be performed in the hand without fistula of patients using light weight and stretching and softening movements. One-hour sports classes will be held at home twice a week for 1 months. Under the supervision of a resident in charge of the eligible plan, patients will perform the relevant exercise programs. A typical class consisted of a 5 to 10 minute warm-up period, 20 to 30 minutes of preparatory exercises, and a 5 to 10 minute cool-down period. In the control group, 58 patients will be monitored for 3 months without performing wrist sports.

Main outcome variables

Clinical maturity of fistula, Ultrasonographic maturity of fistula

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210224050491N2**

Registration date: **2023-03-23, 1402/01/03**

Registration timing: **prospective**

Last update: **2023-03-23, 1402/01/03**

Update count: **0**

Registration date

2023-03-23, 1402/01/03

Registrant information

Name

ghasem mehri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3630

Email address

ghasemmehri1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-05-21, 1402/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of a wrist exercise program on the maturation of arteriovenous fistula and Steele's syndrome in hemodialysis patients

Public title

The effect of a wrist exercise program on the maturation of arteriovenous fistula

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have undergone hemodialysis and Arteriovenous fistula surgery Dialyses at least 2 times a week Age above 18 years

Exclusion criteria:

Suffering from other chronic diseases

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

116 patients are randomly placed in two groups A and B using block randomization method (block of four). Due to having two intervention and control groups in each block, an equal number of states A and B should be placed, and due to the volume of four blocks, there were six different states for the blocks, which are: AABB, ABAB, ABBA BBAA, BABA, BAAB. The different states of the blocks will be written on cardboard cards of the same size and color. Then the obtained sequences are placed in sealed envelopes and the number of 29 cards is randomly selected and arranged again by replacing the blocks, the order of placement of patients in groups A (intervention) and B (control) will specify.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical

Sciences

Street address

Payambar azam complex, Basij Sq., Sardasht Town

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2022-12-11, 1401/09/20

Ethics committee reference number

IR.ARAKMU.REC.1401.265

Health conditions studied

1

Description of health condition studied

Arteriovenous fistula

ICD-10 code

I77.0

ICD-10 code description

Arteriovenous fistula, acquired

Primary outcomes

1

Description

Clinical maturation of arteriovenous fistula

Timepoint

One month after the start of the intervention

Method of measurement

Physical examination

2

Description

Ultrasonographic maturation of arteriovenous fistula

Timepoint

One month after the start of the intervention

Method of measurement

Examination of ultrasound indicators by a radiologist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, 58 patients do an exercise program at home using a CD. Wrist exercises will be performed in the hand without fistula of patients using light weight and stretching and softening movements. One-hour sports classes will be held at home twice a week for 1 month. Under the supervision of a resident in charge of the eligible plan, patients will perform the relevant exercise programs. A typical class

consisted of a 5- to 10-minute warm-up period, 20 to 30 minutes of preparatory exercises, and a 5- to 10-minute cool-down period.

Category

Rehabilitation

2**Description**

Control group: In the control group, 58 patients will be monitored for 1 month without performing wrist sports.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amir-al-momenin hospital

Full name of responsible person

Hamed Motahari

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Payambar azam complex, Basij Sq., Sardasht Town

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mahdi Salehi

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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

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

Hamed Motahari

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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

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Other areas of specialty/work

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

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

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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