Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Feb 2026

Investigating the effect of mixed therapeutic exercises and self-management education with and without functional strength exercises on pain and function factors in patients with avascular necrosis of the femoral head

Protocol summary

Study aim
Comparing the effect of therapeutic exercises and self-management education with and without functional strength exercises on pain-related outcomes, and functional factors in patients with avascular necrosis of the femoral head.

Design
Randomised clinical trial with control group, single-blinded, parallel.

Settings and conduct
Assessments are done at baseline, 3 months after the intervention, and 4 months follow up will be performed in the Tehran, Rheumatology Research Center of Shariati Hospital. Data evaluators and analyzers will be blind to the participants in each group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: male and female between ages of 18–50 years, Diagnosis of avascular necrosis of the femoral head. Exclusion criteria: hip or knee replacement, history of neurological disease, Patients on the waiting list for joint replacement surgery.

Intervention groups
The intervention group includes mixed therapeutic exercises plus functional strength exercises, and self-management education and the control group includes mixed therapeutic exercises and self-management education. self-management education aims to reduce and management of pain and increase self-care with correct choices in the face of pain. mixed therapeutic exercises aim to reduce pain and increase function by improving muscle strength, joint range of motion, mobility of joints, and decreasing rigidity. mixed therapeutic exercises plus functional strength exercises with the goal to will reduce pain more in functional activities and also will improve factors related to the function.

Main outcome variables
Pain; pain in functional activities; factors related to the function.

General information

Reason for update
Based on previous research, which shows a 20% dropout rate in exercise intervention studies, we increased the sample size to 53 patients. Also, the duration of the recruitment end date in this study was increased.

Acronym
AVN

IRCT registration information
IRCT registration number: **IRCT20220510054814N2**
Registration date: **2023-05-30, 1402/03/09**
Registration timing: **prospective**

Last update: **2024-06-03, 1403/03/14**
Update count: **1**

Registration date
2023-05-30, 1402/03/09

Registrant information

Name
Zohreh Gholami

Name of organization / entity
The University of Kharazmi

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-22, 1402/04/01
Expected recruitment end date
2024-07-22, 1403/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of mixed therapeutic exercises and self-management education with and without functional strength exercises on pain and function factors in patients with avascular necrosis of the femoral head

Public title
Investigating the effects of exercise and self-management education on pain and function in patients with avascular necrosis of the femoral head
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of osteonecrosis of the femoral head according to the diagnostic criteria of AVN from grade I to IV (based on ARCO classification criteria) Hip pain/ decreased mobility Ability to read and write and access to a smartphone or tablet Age over 18 years
Exclusion criteria:
Participation in a physical therapy program, and regular exercise therapy during the last 6 months Being on the waiting list for joint replacement surgery (in the next 3 months) Hip/ knee replacement surgery Patients who cannot complete therapeutic exercises for a period of three months Severe osteoporosis Severe medical, neurological, or psychiatric conditions Failure to fill out the consent form Severe osteonecrosis of the knee/ severe knee osteoarthritis
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **53**
Randomization (investigator's opinion)
Randomized
Randomization description
Following the baseline examination, by using the method shown on the website http://randomizer.org/, participants will be randomly assigned to the mixed therapeutic exercises group, and functional strength exercises plus mixed therapeutic exercises group. Simple randomization will be used (1:1). The computer will generate a sequence of random numbers. Created before the start of data collection by a researcher who is not involved in the recruitment or treatment of patients. Another researcher, blind to the baseline examination, processes treatment according to the group assignment. An independent assessor who does not know about the study's hypothesis and methods and is blind to the treatment group assesses the outcome measures before the interventions.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the assessor will be blinded to the study groups. Furthermore, the data obtained from the study will be analyzed by a statistician who is not aware of the patient groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Sport Sciences Research Institute (SSRI)
Street address
Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.
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Postal code
1491115719
Approval date
2023-03-15, 1401/12/24
Ethics committee reference number
IR.SSRC.REC.1401.154

Health conditions studied

1

Description of health condition studied
Avascular necrosis of the femoral head
ICD-10 code
M87
ICD-10 code description
Osteonecrosis

Primary outcomes

1

Description
Pain and pain in functional activities
Timepoint
Will be measured at the baseline, after the end of 3 months intervention, and after the end of 4 months follow up.
Method of measurement
Using a 10 cm numeric pain rating scale during walking and sitting to stand, also pain for the last two weeks

Secondary outcomes

1

Description
Measure of dysfunction
Timepoint
Will be measured at the baseline, after the end of 3 months intervention, and after the end of 4 months follow up.
Method of measurement
Harris Hip Score

2

Description
Pain, stiffness and physical function
Timepoint
Will be measured at the baseline, after the end of 3 months intervention, and after the end of 4 months follow up.
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis index in hip osteoarthritis

3

Description
Physical function
Timepoint
Will be measured at the baseline, after the end of 3 months intervention, and after the end of 4 months follow up.
Method of measurement
Timed up and go (TUG); 30-s chair-stand test

4

Description
Joints range of motion
Timepoint
Will be measured at the baseline, after the end of 3 months intervention, and after the end of 4 months follow up.
Method of measurement
Goniometer

5

Description
Muscles strength
Timepoint
Will be measured at the baseline, after the end of 3 months intervention, and after the end of 4 months follow up.
Method of measurement
Hand-held dynamometer

6

Description
Walking speed
Timepoint
Will be measured at the baseline, after the end of 3 months intervention, and after the end of 4 months follow up.
Method of measurement
10-meter walk test

Intervention groups

1

Description
Control group: Mixed therapeutic exercises: Both groups present in this research will receive the Mixed therapeutic exercises protocol. In this way, after registering the demographic information of the patients and performing the pre-tests, education videos of therapeutic exercises with explanations will be sent to the patients. The patients will be told to send a short video of the exercises to the researcher after starting the first exercise session, so that if there are any movement problems or errors, they can be corrected by the researcher. Also, patients are required to do exercises twice a week for 24 sessions (12 weeks) and record their exercises in the diaries calendar (which will be given to them in the first session) after each exercise session. The researcher will be in contact with the patients every two weeks and will monitor the progress of the exercises. Patients will be instructed to report to the researcher any pain (according to the NRS scale) greater than 7 during the exercises and the day after the exercises. Exercises will be progressive and adjusted according to the patient's condition. The exercises will include 4 to 10 minutes of warming up, then doing resistance exercises and mobility and stretching exercises. Hip joint self-traction will be recommended to patients once a week, and like exercises protocol, education will be sent to patients through a video file. Self-management education: Both groups will receive this education. In this education, patients will be aware of the importance of performing exercise protocols. This education will be personalized in a targeted manner and according to previous studies based on the type of illness of the patients, which include: 1. Encouraging the implementation of therapeutic exercise protocol, 2. Encouraging weight control, 3. Using heat modality around the involved joint, 4. Wearing shoes with a flat surface or shoes with a low heel height, 5. Healthy food

choices and a balanced diet 6. Encouraging sleep regulation 7. Teaching non-pharmacological techniques to reduce pain.

Category

Treatment - Other

2

Description

Intervention group: In this group, in addition to self-management education and therapeutic exercises of the control group, education based on the principles of daily functional activities (sitting and standing up, going up and down stairs, standing, sleeping) as well as exercises based on functional and modified activities such as: half squats, half lunges, step up and down with a low height (10 to 30 cm), standing on one leg with the support of the other leg or with the support of the wall. Patients will be told to do the exercises once a week in addition to the exercises of the control group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology Research Center (RRC), Dr. Shariati Hospital, Tehran University of Medical Sciences (TU

Full name of responsible person

Seyedeh Tahereh Faezi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kharazmi University

Full name of responsible person

Raghad Mimar

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Center for Human Movement Sciences Kharazmi University Mirdamad, Sout Razan Street, Hesari Street, Keshvari Sport Complex, Tehran, Iran

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Grant name

Grant code / Reference number

46795-2-2-1402

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

Yes

Title of funding source

Kharazmi University

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

Kharazmi University

Full name of responsible person

Zohre Gholami

Position

Postgraduate Student

Latest degree

Bachelor

Other areas of specialty/work

Corrective Exercises, prevention of sports injuries and Therapeutic Exercises

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Position
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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
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

Title and more details about the data/document
Only demographic and outcomes-related data will be shared.

When the data will become available and for how long
Access period starts 6 months after the results are published.

To whom data/document is available
Personal information is confidential and general results are available to anyone in the article.

Under which criteria data/document could be used
Information is not available to anyone. General results are available to anyone in the article.

From where data/document is obtainable
Zohreh Gholami Email: Zzohreh.Ggholami@gmail.com

What processes are involved for a request to access data/document
The applicant can request details from the researchers within 7 to 10 days using the message sent by email.

Comments