

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of water-based resistance training with blood flow restriction on functional capacity, heart rate variability, electrical activity of quadriceps muscles and knee joint kinematic while walking in postmenopausal women with knee osteoarthritis.

Protocol summary

Study aim

Determining the effect of resistance training with blood flow restriction in water on functional capacity, heart rate variability, electrical activity of quadriceps muscles and knee joint kinematics during walking in postmenopausal women with knee osteoarthritis

Design

A clinical trial with a control group, with parallel groups (resistance in water, resistance with blood flow restriction), Restricted randomization with a stratified method, on 45 patients with 2nd and 3rd degree arthritis, postmenopausal women, Gpower software was used for the sample size in three groups.

Settings and conduct

Training sessions will be conducted in the culture pool of Qaen city under the supervision of the physiotherapist and the research team. The desired tests will be conducted in the Physiology Laboratory of Birjand University.

Participants/Inclusion and exclusion criteria

Postmenopausal women with grade 2 and 3 arthritis; No history of cardiovascular disease; non-smokers; Not suffering from skin and contagious diseases that can be transmitted by water; not taking non-steroidal and anti-inflammatory drugs in the last 3 months; No injection of corticosteroids in the last 6 months; No surgery or other invasive procedure on the knee in the last 6 months

Intervention groups

The Progressive resistance group in the water by tying weights to the ankles and performing hydrotherapy movements for knee strengthening, The Progressive resistance group with blood flow restriction in the water by tying a cuff around the thigh and tying weights to the ankles and performing hydrotherapy movements for knee strengthening, The Control group did not receive any activities under the supervision of the research

group and did their normal life activities

Main outcome variables

Heart rate variability; Knee kinematic condition while walking; Electrical activity of the quadriceps muscle; Functional capacity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240911063005N1**

Registration date: **2024-09-22, 1403/07/01**

Registration timing: **prospective**

Last update: **2024-09-22, 1403/07/01**

Update count: **0**

Registration date

2024-09-22, 1403/07/01

Registrant information

Name

samaneh baniasadi

Name of organization / entity

University Of Birjand

Country

Iran (Islamic Republic of)

Phone

+98 56 3249 9419

Email address

samaneh_baniasadi@birjand.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01
Expected recruitment end date
2024-11-21, 1403/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of water-based resistance training with blood flow restriction on functional capacity, heart rate variability, electrical activity of quadriceps muscles and knee joint kinematic while walking in postmenopausal women with knee osteoarthritis.

Public title
Comparison of resistance exercises in water with and without blood flow restriction on people with knee osteoarthritis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Postmenopausal women with grade 2 and 3 arthritis
No history of cardiovascular disease
Non-smokers
Absence of skin and contagious diseases that can be transmitted by water
Not taking non-steroidal and anti-inflammatory drugs in the last 3 months
No injection of corticosteroids in the last 6 months
No surgery or other invasive procedure on the knee in the last 6 months
Exclusion criteria:
Menopause of people
Arthrosis degree lower than 2 and higher than 3
History of cardiovascular disease

Age
From **45 years** old to **70 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Limited randomization and stratified method considering homogeneity in anthropometric characteristics (weight, Age of menopause and body mass index in three groups)

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 in Birjand University Research

Street address

Birjand University Campus., University Blvd., at the end of Shahid Avini Boulevard

City

Birjand

Province

South Khorasan

Postal code

9717434765

Approval date

2024-02-21, 1402/12/02

Ethics committee reference number

IR.BIRJAND.REC.1402.016

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Functional capacity

Timepoint

Measurement of functional capacity 48 hours before the start and 48 hours after the end of the study

Method of measurement

Chair stand test, walking speed, timed walking test, 2-minute walk and rise test (TUG) and dynamic balance

2

Description

Heart rate variability

Timepoint

Measurement of heart rate variability 48 hours before the start and 48 hours after the end of the study

Method of measurement

Polar heart rate monitor

3

Description

Electrical activity of quadriceps muscles

Timepoint
Measurement of electrical activity of quadriceps muscles
48 hours before the start and 48 hours after the end of the study

Method of measurement
Electromyography device(EMG)

4

Description
Knee joint kinematics while walking

Timepoint
Measurement of knee joint kinematics while walking 48 hours before the start and 48 hours after the end of the study

Method of measurement
Inertial measurement unit device(IMU)

Secondary outcomes

1

Description
Pain

Timepoint
48 hours before the start and after the end of the study

Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index Questionnaire

Intervention groups

1

Description
Intervention group: Water resistance for 8 weeks and 3 sessions per week with progressive weights and knee therapy exercises

Category
Treatment - Other

2

Description
Intervention group: resistance along with blood flow restriction in water for 8 weeks and 3 sessions every week for 45 minutes, therapeutic knee exercises in water with a cuff around the thigh and weight on the ankle during the main exercises.

Category
Treatment - Other

3

Description
Control group: They do not receive any intervention

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Rheumatology specialist doctor's office

Full name of responsible person
Dr. Zeinab Sarmi

Street address
Shafa doctors building, Taleghani 20

City
birjand

Province
South Khorasan

Postal code
9761771856

Phone
+98 905 534 5420

Email
z.13612002@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University of Birjand

Full name of responsible person
Abulfazl Akbarpour

Street address
Birjand University Campus, University Boulevard, at the end of Shahid Avini Boulevard

City
Birjand

Province
South Khorasan

Postal code
9717434765

Phone
+98 56 3102 2001

Fax
+98 56 3220 2515

Email
akbarpour@birjand.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
The University of Birjand

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**

The University of Birjand

Full name of responsible person

Mohsen Mohammadnia Ahmadi

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Sports physiology

Street address

Birjand University Campus, University Boulevard, at the end of Shahid Avini Boulevard

City

Birjand

Province

South Khorasan

Postal code

9717434765

Phone

+98 56 3102 5000

Email

m.m.ahmadi2005@birjand.ac.ir

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

The University of Birjand

Full name of responsible person

Mohsen Mohammadnia Ahmadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Sports physiology

Street address

Birjand University Campus, University Boulevard, at the end of Shahid Avini Boulevard

City

Birjand

Province

South Khorasan

Postal code

9717434765

Phone

+98 56 3102 5000

Email

m.m.ahmadi2005@birjand.ac.ir

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

The University of Birjand

Full name of responsible person

samaneh baniasadi

Position

PhD student in physical education

Latest degree

Master

Other areas of specialty/work

Sports physiology

Street address

No. 4., between 8 and 10 Abu Talib., Abu Talib Blvd

City

Qaen

Province

South Khorasan

Postal code

9761771856

Phone

+98 56 3249 9419

Email

samaneh_baniasadi@birjand.ac.ir

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available