

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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