Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of six weeks aerobic, resistance, and combined exercises on inflammatory markers, anti-inflammatory markers, cross sectional area , muscle architecture, kinematic and kinetic parameters in overweight moderate hemophilia A patients

Protocol summary

Study aim

Effects of six weeks aerobic, resistance, and combined exercises on inflammatory markers, anti-inflammatory markers, cross sectional area and muscle architecture, kinematic and kinetic parameters in overweight patients moderate hemophilia A

Design

A randomized, controlled, Blood sample, sonography, MRI, kinematic and kinetic assessor-blinded, six-week trial, three times weekly

Settings and conduct

The exercise training and parameters measurement are done in the Department of Physiotherapy,School of Rehabilitation Sciences, IUMS. Muscle thickness and pennation angle is measured using the B-mode ultrasound , cross sectional area using MRI (Axial planes) at 50% of the arm and thigh length. Kinematic parameters using motion analysis (vicon) and kinetic parameters using force plate (kistler) system are measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria:moderate haemophilia A (factor VIII 1% -5 %)؛aged 35–55 years; body mass index 25–30 kg/m2; no history of an inhibitor; Total Hemophilia Joint Health Score (HJHS) ≤10, Factor VIII prophylaxis before and during treatment protocol Exclusion criteria: Clinical signs of active bleeding; Participation in regular physical training activities (more than two times per week) in the previous six months; High blood pressure at rest (systolic >160 mmHg, diastolic >10 mmHg)

Intervention groups

Resistance Exercise Group Aerobic Exercise Group Combined Exercise Group Control Group

Main outcome variables

IL-6, IL-10, TNF. hs-CRP, Adiponectine, muscle thickness, pennation angle, cross section area of biceps, triceps,vastus medialis and vastus lateralis, angular displacement and velocity of joints, mean and standard deviation, velocity and total displacement of center of pressure

General information

Reason for update

Add previously Measured variables with the same proposal, material, methods and study population

Acronym

IRCT registration information

IRCT registration number: **IRCT20180128038541N1**
Registration date: **2018-02-13, 1396/11/24**
Registration timing: **retrospective**

Last update: **2020-04-23, 1399/02/04**
Update count: **1**

Registration date

2018-02-13, 1396/11/24

Registrant information

Name
behrouz parhampour
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2222 8051
Email address
behrouz.parhampour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-21, 1396/07/29

Expected recruitment end date

2018-01-19, 1396/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of six weeks aerobic, resistance, and combined exercises on inflammatory markers, anti-inflammatory markers, cross sectional area , muscle architecture, kinematic and kinetic parameters in overweight moderate hemophilia A patients

Public title

Effects of exercises on inflammatory markers, anti-inflammatory markers, cross sectional area , muscle architecture, kinematic and kinetic parameters in moderate hemophilia A patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Men with moderate haemophilia A (factor VIII 1% -5 %) Aged 35–55 years; Body mass index 25–30 kg/m2; No history of an inhibitor; Total Hemophilia Joint Health Score (HJHS) ≤10 Factor VIII prophylaxis before and during treatment protocol

Exclusion criteria:

Clinical signs of active bleeding Participation in regular physical training activities (more than two times per week) in the previous six months High blood pressure at rest (systolic >160 mmHg, diastolic >10 mmHg)

Age

From **35 years** old to **55 years** old

Gender

Male

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The probability sampling method is simple randomization.Randomization was performed by an external observer using closed envelopes in blocks of 8, each assigned to two subjects

Blinding (investigator's opinion)

Single blinded

Blinding description

The person collecting , determining the blood samples, sonography and MRI measurements, kinematic parameters, kinetic parameters and data analyser and Data Saftey and Monitoring Committee are blinded to the grouping, but the physiotherapist for training(researcher) and participants is not masked to the group assignment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Nezam Alley, Shahnazari Street, Mirdamad Street, School of Rehabilitation. IUMS

City

Tehran

Province

Tehran

Postal code

1545913187

Approval date

2016-06-28, 1395/04/08

Ethics committee reference number

IR.IUMS.REC.1395.9211342206

Health conditions studied

1

Description of health condition studied

Moderate Hemophilia A

ICD-10 code

D66

ICD-10 code description

Hereditary factor VIII deficiency

Primary outcomes

1

Description

IL-6: Inflammatory marker

Timepoint

Before and after six weeks exercise

Method of measurement

ELISA kit, Invitrogen, San Diego,USA

2

Description

TNF: Inflammatory marker

Timepoint
Before and after six weeks exercise
Method of measurement
ELISA kit, Invitrogen, San Diego,USA

3

Description
hs-CRP:Inflammatory marker
Timepoint
Before and after six weeks exercise
Method of measurement
ELISA kit, Invitrogen, San Diego,USA

4

Description
IL-10: Anti inflammatiry marker
Timepoint
Before and after six weeks exercise
Method of measurement
ELISA kit, Invitrogen, San Diego,USA

5

Description
Adiponectine: Anti inflammatiry marker
Timepoint
Before and after six weeks exercise
Method of measurement
ELISA kit, Invitrogen, San Diego,USA

6

Description
Muscle Thickness and pennation angle
Timepoint
Before and after six weeks exercise
Method of measurement
Ultrasonography, B mode

7

Description
Muscle cross sectional area
Timepoint
Before and after six weeks exercise
Method of measurement
Axial plane scans using MRI scanner

8

Description
Angular displacement and velocity of the knee and hip joints in three planes including sagital, frontal and transverse planes
Timepoint
Before and after six weeks exercise
Method of measurement
Marking the knee and hip joints and recording by the camera of the motion analysis (Vicon)

9

Description
Mean, standard deviation, total displacement and velocity of center of pressure during walking and sit to stand in the frontal and sagital planes
Timepoint
Before and after six weeks exercise
Method of measurement
Force plate (Kistler) With a sampling rate of 100 Hz

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Resistanve exercise: Resistance training group require to perform six weeks trunk, upper and lower limb exercises (65-75% 1RM) , 40 min per session , three days per week.Strength-training exercises consist of knee flexion, knee extension, shoulder press, chest press, leg press, calf raise, and squat. Subjects perform 10 repetitions of each exercise during the first, third and fifth weeks and 12 repetitions of each exercise during the second, fourth and sixth weeks of training.
Category
Rehabilitation

2

Description
Intervention group 2: Aerobic exercise: Aerobic exercise perform on treadmill and cycle ergometer . Aerobic exercise intensity is adjusted based on maximum heart rate (220 - age = MHR). In the first, second, and third of each two-week period, the target intensity is 65%, 70%, and 75% of MHR,respectively. Each exercise session consist of aerobic training on a treadmill for 22 minutes ,and cycle ergometer for 22 minutes. Each step include warm up, training at constant workload, and cool down. A 3-minute warm-up phase followed by 12 minutes training at constant workload phase and a 2-minute cool down phase is used for the aerobic exercises.
Category
Rehabilitation

3

Description
Intervention group3: Combined exercise:In the combined resistance with aerobic training group, the intensity of the resistance exercises is similar to that for the resistance training group, but there is five repetitions of each exercise in the first, third, and fifth weeks and six repetitions during the second, fourth, and sixth weeks of training. After 22 minutes of aerobic exercises, patients perform 20 minutes resistance exercises. Each exercise session consisted of aerobic training on a treadmill for 11 minutes ,and cycle ergometer for 11 minutes. Each step

include warm up, training at constant workload, and cool down. A 3-minute warm-up phase followe by 6 minutes training at constant workload phase and a 2-minute cool down phase is used for the aerobic exercises.

Category
Rehabilitation

4

Description
Control group: The control group is requested not to change their daily physical activity during the 6 weeks.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Iraninan Comprehensive Hemophilia Treatment Center

Full name of responsible person
Behrouz Parhampour

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No 543, Zartosht - Phelestine Street, Fatemi Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Behnoosh Vasaghi Gharamaleki

Position
Assistance Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Full name of responsible person
Behnoosh Vasagh Gharamaleki

Position
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Latest degree
Ph.D.

Other areas of specialty/work
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Latest degree

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Other areas of specialty/work

Physiotherapy

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Email

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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

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

Information about serum markers, MSK sonography and MRI, kinematic and kinetic parameters

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Physiotherapist and orthopadist related with hemophilia patients

Under which criteria data/document could be used

Coopration for article publishing using our data for investigation of effect of exercise with more duration on the muscle cross section area and architecture, kinematic and kinetic parameters

From where data/document is obtainable

Behrouz Parhampour, first email and then call phone: 02144925035 behrouz.parhampour@gmail.com

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

Sending email and answering within 2 next weeks

Comments