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
Expected recruitment end date
2018-01-19, 1396/10/29

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

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

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

Placebo
Not used

Assignment
Parallel

Secondary Ids
empty

Health conditions studied

Description of health condition studied
Moderate Hemophilia A

ICD-10 code
D66

ICD-10 code description
Hereditary factor VIII deficiency

Primary outcomes

Description
IL-6: Inflammatory marker

Timepoint
Before and after six weeks exercise

Method of measurement
ELISA kit, Invitrogen, San Diego, USA

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

5
Description
Adiponectin: Anti inflammatory 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: Resistance 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 group 3: 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
Iranian Comprehensive Hemophilia Treatment Center
Full name of responsible person
Behrouz Parhampour
Street address
No 543, Zartosht - Phelestine Street, Fatemi Square
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1415863675
Phone
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Email
behrouz.parhampour@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mojtaba Kamyab
Street address
Nezam Alley, Shahnazari Street, Mirdamad Street, School of Rehabilitation. IUMS
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1545913187
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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
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Full name of responsible person
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Street address
Nezam Alley, Shahnazari Street, Mirdamad Street, School of Rehabilitation. IUMS
City
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**
Cooperation 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**