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 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
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 Safety 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-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 sagittal, 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 followed 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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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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Province
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Postal code
1545913187
Phone
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Email
kamyab.m@iums.ac.ir

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
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
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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Assistance Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
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
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