

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### comparing effect of traditional continuous training and high intensity interval training on cardiac hypertrophic indexes, PI3k gene expression and cardiac function

#### Protocol summary

##### Summary

The aim of this study is to investigate possible heart hypertrophy, as a result of training (Traditional and HIT) based on the path defined for clinical observed (echocardiography), measuring proteins associated with hypertrophy (IGF-I and PI3K) as well as measuring gene expression in leukocytes p110 $\delta$  is the genomic level. Design Randomized controlled quasi-experimental study that was conducted on 36 students. Inclusion criteria is male gender, and having age between 20-30 years and being in the normal range of body mass index and exclusion criteria of the research history of professional sports as well as the current regular exercise, no smoking, no disease cardiovascular, pulmonary, metabolic and musculoskeletal as well as any injury that impair the implementation of physical activity.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201603039460N2**

Registration date: **2016-03-31, 1395/01/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-03-31, 1395/01/12

##### Registrant information

##### Name

Arash Saadatnia

##### Name of organization / entity

Shahid Beheshti university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2990 2940

##### Email address

a\_saadatnia@sbu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2014-09-21, 1393/06/30

##### Expected recruitment end date

2014-10-07, 1393/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparing effect of traditional continuous training and high intensity interval training on cardiac hypertrophic indexes, PI3k gene expression and cardiac function

##### Public title

comparing effect of traditional continuous training and high intensity interval training on cardiac morphology and function

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

inclusion criteria include age between-30, male gender and being in BMI normal range. Exclusion criteria include professional athletics history as well as the current regular exercise, smoking, cardiovascular and metabolic disease or any complication that disrupt the implementation of exercise

##### Age

From **20 years** old to **30 years** old

**Gender**  
Male

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **36**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
we use random numbers table to assigning subjects into three groups randomly

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Ferdowsi University of Mashhad,  
Mashhad, Iran

##### Street address

Azadi ave

##### City

mashhad

##### Postal code

978646342

#### Approval date

2013-09-21, 1392/06/30

#### Ethics committee reference number

19868

## Health conditions studied

### 1

#### Description of health condition studied

healthy subjects which participate in physical activity

#### ICD-10 code

Z00.8

#### ICD-10 code description

Health examination in population surveys

## Primary outcomes

### 1

#### Description

VO2max

#### Timepoint

pre intervention- post intervention

#### Method of measurement

Bruce treadmill test

### 2

#### Description

Stroke Volume

#### Timepoint

pre intervention- post intervention

#### Method of measurement

echocardiography

### 3

#### Description

ejection Fraction

#### Timepoint

pre intervention- post intervention

#### Method of measurement

echocardiography

### 4

#### Description

Left ventricle volume

#### Timepoint

pre intervention- post intervention

#### Method of measurement

echocardiography

### 5

#### Description

End of systolic volume

#### Timepoint

pre intervention- post intervention

#### Method of measurement

echocardiography

### 6

#### Description

End of diastolic volume

#### Timepoint

pre intervention- post intervention

#### Method of measurement

echocardiography

### 7

#### Description

inter ventricular septum

#### Timepoint

pre intervention- post intervention

#### Method of measurement

echocardiography

**8**

**Description**

plasma IGF-I levels

**Timepoint**

pre intervention- post intervention

**Method of measurement**

ELISA Kit

**9**

**Description**

PI3K activity

**Timepoint**

pre intervention- post intervention

**Method of measurement**

ELISA Kit

**10**

**Description**

p110δ Gene expression in leukocytes

**Timepoint**

pre intervention- post intervention

**Method of measurement**

PCR

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention 1: HIT group Exercises included warm up, HIT training, cool down. Subjects warmed up by stretching and easy walking for 5 minutes. The HIT interventions consisted of four 30 s maximal effort (“all-out”) shuttle run bouts (from cone-1 to cone-2 ,20 meter sweep) separated by 1.5 min passive rest each . HIT protocol began with 4 cycles/session and every two weeks added one cycle. Finally it was 8 cycles/session in tenth week that lasted 16 minutes. Cooling Down also included 5 min of walking and stretching. During the HIT interventions all subjects were vocally encouraged to maintain Maximal effort.

**Category**

Other

**2**

**Description**

Intervention 2: consists of 20 minutes of running continuously at heart rate of approximately 140 continuously that started three sessions per week for fourth weeks and gradually increased in tenth week to 40 minutes.

**Category**

Other

**3**

**Description**

control: Control group asked to be sedentary in this period.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ferdowsi University of Mashhad

**Full name of responsible person**

Arash Saadatnia

**Street address**

Azadi ave

**City**

mashhad

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid beheshti university

**Full name of responsible person**

Dr arsh saadatnia

**Street address**

velenjak

**City**

tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid beheshti university

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

empty

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University

**Full name of responsible person**

arash saadatnia

**Position**

PHD

**Other areas of specialty/work**

**Street address**

Shahid Beheshti University, Velenjak, Tehran, I.R.  
IRAN

**City**

tehran

**Postal code**

1983969411

**Phone**

+98 212293615

**Fax**

**Email**

arash.denatation@gmail.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University

**Full name of responsible person**

khosrow ebrahim

**Position**

Professor

**Other areas of specialty/work**

**Street address**

Shahid Beheshti University, Velenjak, Tehran, I.R.  
IRAN

**City**

tehran

**Postal code**

1983969411

**Phone**

+98 212294323

**Fax**

**Email**

k-ebrahim@sbu.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University

**Full name of responsible person**

arash saadatnia

**Position**

PHD Candidate

**Other areas of specialty/work**

**Street address**

Shahid Beheshti University, Velenjak, Tehran, I.R.  
IRAN

**City**

tehran

**Postal code**

1983969411

**Phone**

+98 21 2990 2761

**Fax**

**Email**

arash.denatation@gmail.com

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*