Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparing the acute effects of resistance exercise with intensity of 50%1RM and 75%1RM on heart rate variability in patients with heart failure

Protocol summary

Study aim
comparing the acute effects of resistance exercise with the intensity of 50%1RM and 75%1RM on autonomic function, cardiac function and functional status of patients with heart failure

Design
Three-arm parallel-group randomized-controlled trial with blinded patients, concealed randomization sequence

Settings and conduct
Due to the fact that the Persian form of the subjective exercise experience scale is not available, the validity and reliability of this scale were examined among a healthy matched control population of 128 volunteer adults who will request to walk for 30 minutes after consent. The eligible patients refer to the hospital after signing informed consent and will be evaluated for autonomic function, cardiac function, functional status, and their psychological response to exercise, then allocate to one of the 3 groups randomly. The intervention consists of a single session resistance exercise and at the end of the intervention again will be evaluated for the above-mentioned variables.

Participants/Inclusion and exclusion criteria
class II, III of stable patients with heart failure, duration of disease:1-4 years, BMI: 25-32kg/m2, optimal medical treatment, the ability of communication; pacemaker, cardiac surgery during last 6 months, myocardial infarction during last year, personal withdrawal

Intervention groups
1-resistance training with intensity of 50%1RM + aerobic training 2--resistance training with intensity of 75%1RM+ aerobic training 3-control group(aerobic training)

Main outcome variables
Heart rate variability(time and frequency dominants), hemodynamics (heart rate, blood pressure, rate pressure product), subjective exercise experiences scale, six minute walking test distance

General information

Reason for update
We have to change the project to some extent because of the Coronavirus and stoping the project due to the traffic ban for high-risk patients like heart failure.

Acronym

IRCT registration information
IRCT registration number: **IRCT20190605043821N1**
Registration date: **2019-08-06, 1398/05/15**
Registration timing: **prospective**

Last update: **2021-01-04, 1399/10/15**
Update count: **1**

Registration date
2019-08-06, 1398/05/15

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-07, 1398/05/16

Expected recruitment end date
2021-03-06, 1399/12/16

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the acute effects of resistance exercise with intensity of 50%1RM and 75%1RM on heart rate variability in patients with heart failure

Public title
effects of resistance training on heart rate variability in patients with heart failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
class II, III of stable heart failure patients stable and optimal medical treatment BMI 25-35 kg/m2 Hemoglobin >12(women) and >13(men) duration of heart failure: 1-4 years Ejection Fraction: <40% age : 45-75 year
Exclusion criteria:
unstable conditions such as complex ventricular arrhythmia, unstable angina pacemaker myocardial infarction during last year cardiac surgery during last 6 months impairment in which exercise is not safe such as orthopedic ... cognitive impairments
Age
From **45 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **19**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization by closed envelops A person blinded to the research provide 57 envelops for 3 groups (19 envelopes for each group) in a box and then exclude one envelope randomly for each patient without replacement
Blinding (investigator's opinion)
Single blinded
Blinding description
The data analyzer is not aware of the treatment performed for individuals
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
thics committee of Tarbiat Modares University of Medical Sciences
Street address
Jalal ale ahmad highway
City
Tehran
Province
Tehran
Postal code
14115111
Approval date
2019-08-03, 1398/05/12
Ethics committee reference number
IR.MODARES.REC.1398.071

Health conditions studied

1

Description of health condition studied
heart failure
ICD-10 code
I50.2
ICD-10 code description
Systolic (congestive) heart failure

Primary outcomes

1

Description
heart rate variability(time and frequency domain)
Timepoint
before and immediately after the intervention
Method of measurement
ECG Holter monitoring

2

Description
Quality of Life
Timepoint
before the intervention
Method of measurement
Minnesota Living with Heart Failure(MLHF) Questionnaire

3

Description
Dyspnea
Timepoint
before the intervention
Method of measurement
Modified Medical Research Council Dyspnea Scale(MRC)

4

Description
Fatigue severity
Timepoint
before the intervention
Method of measurement
Fatigue Severity Scale (FSS)

5

Description
blood pressure
Timepoint
before and immediately after the intervention
Method of measurement
sphygmomanometer

6

Description
heart rate
Timepoint
before and immediately after the intervention
Method of measurement
Qardio-core and ECG Holter monitoring

7

Description
muscle strength
Timepoint
before and immediately after the intervention
Method of measurement
Digital dynamometery

8

Description
Rate Pressure Product
Timepoint
before and immediately after the intervention
Method of measurement
heart rate×systolic blood pressure

9

Description
psychological response to the exercise stimulus
Timepoint
before and immediately after the intervention
Method of measurement
subjective exercise experience scale (SEES)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: resistance exercise with the intensity of 50%1RM: a single exercise session includes 5 minutes warm-up, 15 minutes of aerobic exercise with the intensity of 50% heart rate reserve, 30 minutes of resistance training (50%1RM) using weights for upper and lower limbs (10 exercises, 2 sets of 6-8 repetitions with 1-minute rest between sets and exercises), and 5 minutes cool down
Category
Rehabilitation

2

Description
Intervention group2: resistance exercise with the intensity of 75%1RM: a single exercise session includes 5-minutes warm-up, 15 minutes of aerobic exercise with the intensity of 50% heart rate reserve, 30 minutes of resistance exercise (75%1RM) using weights for upper and lower limbs (10 exercises, 2 sets of 6-8 repetitions with 1-minute rest between sets and exercises), and 5 minutes cool down
Category
Rehabilitation

3

Description
Control group: a single session exercise includes 5 minutes warm up, 15 minutes aerobic exercise with intensity of 50% heart rate reserve, and 5 minutes cool down
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tarbiat Modares University
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
Tarbiat Modares University
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
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Roya Ravanbod
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assistant professor
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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
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
There is not any more information
When the data will become available and for how long
There is not any more information
To whom data/document is available
There is not any more information
Under which criteria data/document could be used
There is not any more information
From where data/document is obtainable
There is not any more information
What processes are involved for a request to access data/document
There is not any more information
Comments
There is not any more information