Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of neuromuscular electrical stimulation, light resistance training, and their combination versus control group on markers of mitochondrial biogenesis, cellular pyroptosis, and hemodynamic stability in hemodialysis patients with cardiorenal syndrome: a randomized clinical trial

Protocol summary

Study aim
To assess the effect of neuromuscular electrical stimulation, light resistance training, and their combination versus control group on markers of mitochondrial biogenesis, cellular pyroptosis, and hemodynamic stability in hemodialysis patients with cardiorenal syndrome

Design
This is a randomized clinical trial with a control group with parallel groups without blinding, in which 40 eligible patients will be randomly assigned to the intervention and control groups using drawing of lots.

Settings and conduct
This study will be conducted at the Beheshti Hospital in Hamadan, involving 40 eligible hemodialysis patients with cardiorenal syndrome. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. Blinding is not feasible in this trial.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age 18 to 75 years; Chronic kidney disease with regular hemodialysis for at least three months; Cardiorenal syndrome; Ability to perform exercise movements and receive neuromuscular electrical stimulation (NMES). Exclusion Criteria: Chest pain, abnormal shortness of breath, or suspected arrhythmia; Dizziness or symptomatic hypotension; Skin burns or infections at the site of electrical stimulation.

Intervention groups
Intervention Group 1: A light resistance training program Intervention Group 2: Neuromuscular electrical stimulation (NMES) Intervention Group 3: Both interventions: the light resistance training program combined with neuromuscular electrical stimulation (NMES) Control group: Routine care and treatment for hemodialysis patients.

Main outcome variables
Primary outcome: PGC-1α levels, SIRT1 enzymatic activity, NLRP3 levels, Caspase-1 enzymatic activity, IL-18 concentration, Blood pressure, BUN concentration, Serum creatinine concentration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N629**
Registration date: **2026-11-12, 1405/08/21**
Registration timing: **prospective**

Last update: **2026-11-12, 1405/08/21**
Update count: **0**

Registration date
2026-11-12, 1405/08/21

Registrant information

Name
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Name of organization / entity
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Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-12-01, 1405/09/10
Expected recruitment end date
2027-01-30, 1405/11/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of neuromuscular electrical stimulation, light resistance training, and their combination versus control group on markers of mitochondrial biogenesis, cellular pyroptosis, and hemodynamic stability in hemodialysis patients with cardiorenal syndrome: a randomized clinical trial

Public title
Effect of neuromuscular electrical stimulation, light resistance training, and their combination versus control group on cellular markers, and hemodynamic stability in hemodialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 75 years; Chronic kidney disease with regular hemodialysis for at least three months; Cardiorenal syndrome; Ability to perform exercise movements and receive neuromuscular electrical stimulation (NMES).
Exclusion criteria:
Chest pain, abnormal shortness of breath, or suspected arrhythmia; Dizziness or symptomatic hypotension; Skin burns or infections at the site of electrical stimulation.
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation of patients to intervention and control groups by lottery. For this purpose, we prepare two sheets, write "intervention" on one and "control" on the other. Then, with each patient's visit, one of the sheets is randomly taken and the patient is assigned to the intervention or control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University, Hamadan Branch
Street address
Vice-chancellor for Research and Technology, Islamic Azad University, Hamadan Branch, Professor Moosivand Ave
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Hamadan
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6518115743
Approval date
2026-10-24, 1405/08/02
Ethics committee reference number
IR.IAU.H.REC.1405.083

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
I95.3
ICD-10 code description
Hypotension of hemodialysis

Primary outcomes

1

Description
PGC-1α levels
Timepoint
Before the intervention and at the end of the eighth week
Method of measurement
Measured via ELISA in cell samples

2

Description
SIRT1 enzymatic activity
Timepoint
Before the intervention and at the end of the eighth week
Method of measurement

Measured via a fluorometric enzymatic activity assay

3

Description
NLRP3 levels
Timepoint
Before the intervention and at the end of the eighth week
Method of measurement
Measured via ELISA in cell samples

4

Description
Caspase-1 enzymatic activity
Timepoint
Before the intervention and at the end of the eighth week
Method of measurement
Measured via an enzymatic activity assay

5

Description
IL-18 concentration
Timepoint
before the intervention and at the end of the eighth week
Method of measurement
Measured via ELISA in blood serum samples

6

Description
Blood pressure
Timepoint
Before the intervention and at the end of the eighth week
Method of measurement
Measured using a sphygmomanometer

7

Description
BUN concentration
Timepoint
Before the intervention and at the end of the eighth week
Method of measurement
Measured via the enzymatic urease method in blood serum samples

8

Description
Serum creatinine concentration
Timepoint
Before the intervention and at the end of the eighth week
Method of measurement
Measured via a standard enzymatic method in blood serum samples

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Routine care and treatment for hemodialysis patients, plus a light resistance training program (including exercises for the biceps, triceps, knee flexion, hamstrings, glutes, quadriceps, and calf/ankle muscles), three sessions per week for 8 weeks.
Category
Treatment - Other

2

Description
Intervention Group 2: Routine care and treatment for hemodialysis patients, plus neuromuscular electrical stimulation (NMES) applied to the quadriceps muscles bilaterally (using an NMES device at a frequency of 50 Hz; 10 seconds of stimulation followed by 20-second intervals, for a total duration of 20–30 minutes), three sessions per week for 8 weeks.
Category
Treatment - Other

3

Description
Intervention Group 3: Routine care and treatment for hemodialysis patients, plus both interventions: the light resistance training program (including exercises for the biceps, triceps, knee flexion, hamstrings, glutes, quadriceps, and calf/ankle muscles) combined with neuromuscular electrical stimulation (NMES) applied to the quadriceps muscles bilaterally (using an NMES device). A frequency of 50 Hz applied for 10 seconds, with 20-second intervals, for a duration of 20 to 30 minutes, three sessions per week, over a period of 8 weeks.
Category
Treatment - Other

4

Description
Control group: Routine care and treatment for hemodialysis patients.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital in Hamadan
Full name of responsible person

Samira Mehrabipour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
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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
Islamic Azad 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
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available