Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Safety, feasibility, and impact of ten weeks of supervised progressive resistance training of lower limbs on select functional, biomechanical, and blood biomarker factors in ambulatory adults with SMA type 3 and quality of life.

Protocol summary

Study aim

This study evaluates the safety and feasibility of progressive lower limb resistance training in individuals with SMA type 3. It also examines effects on functional performance, static balance, gait parameters, ankle joint mobility, isometric muscle strength, quality of life, fatigue (via FSS), and blood biomarkers including creatine kinase, IL-6, IFN-γ, and TNF-α.

Design

In this study, two groups will be divided into research and control groups after being placed in two age categories using traditional lottery methods (writing names on paper). Considering the rarity of accessible patients, the sample size will be based on what is available and the willingness to participate in this project, within a radius of 100 kilometers from the research site

Settings and conduct

This study is conducted at the multidisciplinary center of Shariati Hospital in Tehran and its occupational therapy department, where patients receive supervised interventions for a duration of ten weeks.

Participants/Inclusion and exclusion criteria

nclusion criteria: Individuals aged ≥18 years with confirmed homozygous deletion of exon 7 in the SMN1 gene, clinical diagnosis of SMA type 3, and ability to walk independently for at least 25 meters. Exclusion criteria: History of surgery or fracture in the past six months, other chronic comorbidities, moderate to severe scoliosis, non-ambulatory SMA or SMA types other than type 3, and participation in other research studies.

Intervention groups

The interventions include supervised progressive resistance training of the lower limbs in the experimental group, while the control group continues their usual daily activities.

Main outcome variables

Muscle strength; functional performance; serum creatine kinase; interleukin-6 (IL-6); interferon-gamma (IFN-γ); tumor necrosis factor-alpha (TNF-α); quality of life.

General information

Reason for update

The sampling date in this RCT has been updated, as the collection process was conducted earlier than originally scheduled. This modification only concerns the timing of sampling and does not affect the methodology, inclusion/exclusion criteria, or other aspects of the protocol.

Acronym

IRCT registration information

IRCT registration number: **IRCT20251113067980N1**
Registration date: **2025-11-26, 1404/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-03, 1404/09/12**
Update count: **1**

Registration date

2025-11-26, 1404/09/05

Registrant information

Name
Shahram Khorshidi
Name of organization / entity
Faculty of Sport Sciences and Health, University of Tehran
Country
Iran (Islamic Republic of)
Phone
+98 21 8835 1730
Email address
shahram.khorshidi@ut.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-12-05, 1404/09/14
Expected recruitment end date
2025-12-05, 1404/09/14
Actual recruitment start date
2025-11-26, 1404/09/05
Actual recruitment end date
2025-11-28, 1404/09/07
Trial completion date
empty

Scientific title
Safety, feasibility, and impact of ten weeks of supervised progressive resistance training of lower limbs on select functional, biomechanical, and blood biomarker factors in ambulatory adults with SMA type 3 and quality of life.

Public title
The effect of exercise on SMA type 3 patients.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age ≥18 years. Homozygous deletion of exon 7 of the SMN1 gene, confirmed by a test report and a specialist physician, indicating SMA type 3 Ability to walk independently for at least 25 meters informed consent
Exclusion criteria:
History of surgery or fracture in the past six months Moderate or severe scoliosis Serum creatine kinase (CK) levels of participants above 1000 units per liter in the past three months Non-ambulatory Under the age of eighteen years The presence of any concurrent chronic diseases such as diabetes, cardiovascular diseases, kidney disease, etc. Any type of SMA other than type 3
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Actual sample size reached: **14**
Randomization (investigator's opinion)
Randomized
Randomization description
To ensure age homogeneity within the study population, participants will be categorized into two age groups (18-29 years and 30+) and randomly assigned to either the control or intervention group using a manual lottery-based randomization method, ensuring a balanced age distribution for subsequent analyses.
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 in Research, Faculty of Physical Education and Sport Sciences, University of Tehran
Street address
culty of Physical Education and Sport Sciences, University of Tehran, North Kargar Street, Central Campus, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1439813117
Approval date
2023-05-20, 1402/02/30
Ethics committee reference number
IR.UT.SPORT.REC.1402.023

Health conditions studied

1

Description of health condition studied
Spinal Muscular Atrophy Type 3
ICD-10 code
G12.1
ICD-10 code description
Other inherited spinal muscular atrophy

Primary outcomes

1

Description
Muscular strength, referring to maximum voluntary isometric contraction; Function, referring to the Timed Up and Go (TUG) test, the Six-Minute Walk Test (6MWT), and the Hammersmith Functional Motor Scale Expanded (HFMSE); Quality of Life Questionnaire; Blood Biomarkers including Interleukin 6, Interferon Gamma, Tumor Necrosis Factor Alpha
Timepoint
Measurement time points will be at the beginning of the study (before the start of the intervention) and at the end of the study
Method of measurement
Handheld dynamometer for muscle strength and for

functional tests according to instructions. For quality of life, the SF-36 questionnaire, and for blood biomarkers, the ELISA method and the Zellbio Germany kit

Secondary outcomes

1

Description
Static balance, spatial and temporal gait parameters, dorsiflexion and plantar flexion angle, blood creatine kinase level, fatigue score
Timepoint
All variables at the beginning and end of the intervention were only creatine kinase levels at the beginning of the study, week 5, and at the end of the intervention
Method of measurement
For static balance, use a force plate; for spatiotemporal gait parameters, use a camera with a frame rate of 60 Hz; for dorsiflexion and plantar flexion angles, use a goniometer; for creatine kinase levels, use the ELISA method; for fatigue, use the Fatigue Severity Scale (FSS) questionnaire

Intervention groups

1

Description
Intervention group: Intervention group: Progressive resistance exercises for the lower extremities in closed and open kinetic chains, supervised and for the first five weeks, twice a week, and for the second five weeks, three times a week, and individually at a specific time for each person, with a trainer-to-trainee ratio of two to one
Category
Rehabilitation

2

Description
Control group: No intervention will be administered to the control group, and participants will continue their usual daily activities without restriction. Should the intervention prove effective and be confirmed by a specialist physician, the same protocol implemented in the research group will be offered under identical conditions and at the same location to members of the control group, on a voluntary basis and according to each participant’s preference. It should be noted that, for those control group participants who wish to receive the intervention after completion of the study, these services will be provided free of charge.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Shariati Educational, Research and Therapeutic Center
Full name of responsible person
Shahram Khorshidi
Street address
Dr. Shariati Hospital, North Kargar Street, Jalal Al-Ahmad Crossroad, opposite the Faculty of Economics, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
shahram.khorshidi@ut.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Tehran
Full name of responsible person
Dr. Manouchehr Moradi Sabzevar
Street address
Central Administration, 16th Azar St., Enghelab Sq., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417935840
Phone
+98 21 6649 7999
Email
moradih@ut.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of Tehran
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
Faculty of Sport Sciences and Health, University of Tehran

Full name of responsible person
Shahram Khorshidi

Position
Non-academic Specialist

Latest degree
Master

Other areas of specialty/work
Biomechanics and Sports Injury

Street address
Faculty of Sport Sciences and Health, University of Tehran, North Campus (Pardis-e Shomali), North Kargar Street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1439813117

Phone
+98 21 8835 1730

Email
shahram.khorshidi@ut.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Faculty of Sport Sciences and Health, University of Tehran

Full name of responsible person
Khadijeh Sohrabi

Position
non-academic specialist

Latest degree
Master

Other areas of specialty/work
Exercise Physiology

Street address
Faculty of Sport Sciences and Health, University of Tehran, North Campus (Pardis-e Shomali), North Kargar Street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1439813117

Phone
+98 21 8835 1730

Email
khadije.sohrabi@ut.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Faculty of Sport Sciences and Health, University of Tehran

Full name of responsible person
Shahram Khorshidi

Position
non-academic specialist

Latest degree
Master

Other areas of specialty/work
Biomechanics and sports injury

Street address
Faculty of Sport Sciences and Health, University of Tehran, North Campus (Pardis-e Shomali), North Kargar Street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1439813117

Phone
+98 21 8835 1730

Email
shahram.khorshidi@ut.ac.ir

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

Clinical Study Report
Yes - There is 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
Yes - There is a plan to make this available

Title and more details about the data/document
The following documents will be shared after study completion and final approvals: the full study protocol, the statistical analysis plan, a de-identified version of the informed consent form, the final clinical study report, and the data dictionary. These materials will include methodological details, statistical procedures, variable definitions, and non-identifiable participant information. Access will be granted to qualified researchers upon formal request and in accordance with ethical and institutional guidelines.

When the data will become available and for how long
Access to the listed documents—including the full study protocol, statistical analysis plan, de-identified informed consent form, final clinical study report, and data dictionary—will begin 6 months after publication of the

main study results and remain available for 2 years to qualified researchers upon formal request

To whom data/document is available

Access to the shared documents will be granted only to researchers and professionals affiliated with academic institutions, recognized research centers, or scientific organizations working in the fields of sports science, rehabilitation, or biomechanics. Applicants must demonstrate relevant research background and clearly state the intended purpose of data use.

Under which criteria data/document could be used

The shared data and documents may only be used for research, educational, or technology development purposes in fields related to sports science, rehabilitation, and biomechanics. Secondary analyses, meta-analyses, or methodological reviews are permitted only if they are conducted with clearly defined scientific objectives, without any attempt to re-identify participants, and in full compliance with ethical and legal standards. Requests must include the applicant's full affiliation, intended use, proposed type of analysis, and a formal commitment to data confidentiality. All requests will be reviewed and approved by the research team and relevant oversight bodies.

From where data/document is obtainable

Interested applicants may submit a formal request via email to one of the study team members: • Shahram Khorshidi Email: shahram.khorshidi@ut.ac.ir • Khadije Sohrabi Email: khadije.sohrabi@ut.ac.ir Requests must include the applicant's full affiliation, intended purpose of use, type of document requested, and a signed commitment to confidentiality and ethical compliance.

What processes are involved for a request to access data/document

Upon receiving a formal request, the research team will review the application within two working weeks. The review will assess the applicant's scientific qualifications, the stated purpose of use, the proposed type of analysis, and the commitment to confidentiality and ethical compliance. If approved, a data use agreement outlining the terms and limitations will be sent for signature. Once the signed agreement is received, the requested documents or data will be delivered within one working week via email or a secure data transfer platform.

Comments