

# 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- $\gamma$ , and TNF- $\alpha$ .

#### 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

Inclusion criteria: Individuals aged  $\geq 18$  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- $\gamma$ ); tumor necrosis factor-alpha (TNF- $\alpha$ ); 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  $\geq 18$  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 (HFMSSE); 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 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**