Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Researching the efficacy of using Electrical Stimulation on the muscle changes caused by the immobility of the dominant leg due to ankle sprain

Protocol summary

Study aim
Determining the effect of using neuromuscular electrical stimulation in preventing atrophy caused by not using muscles during leg immobility due to ankle sprain

Design
A clinical trial with a control group, with parallel groups, unblinded, randomized, on 20 patients. A simple randomization method was used.

Settings and conduct
Subjects are randomly divided into two groups: control or neuromuscular electrical stimulation . Patients in both groups, after going to the emergency room and performing initial evaluations , are placed in a brace for ankle sprains and enter the muscle disuse period for 3 weeks, either with the NMES group. and without group , (NMES) (twice a day under supervision at home). The required evaluations are performed in two time periods, the first in the same emergency room during hospitalization and then 3 weeks after the start of the immobilization period, in the form of a combination of clinical and paraclinical evaluations, which include checking the function and volume of muscle mass, as well as checking the level Serum is blood sugar and blood insulin

Participants/Inclusion and exclusion criteria
Inclusion criteria: dominant ankle sprain Exclusion criteria: BMI less than 18.5 or more than 30 kg/m2; Any back, knee or shoulder complaints that may interfere with the use of crutches; Type 2 diabetes determined by HBAc1 values >7.0% family history of thrombosis; severe heart problems; People who have done structured and long-term resistance training during the 6 months before the study; People with neurological, muscular problems or previous trauma

Intervention groups
Intervention group: For people assigned to this group, two sessions of NMES were performed every day during 3 weeks of immobility at home. Neuromuscular electrical stimulation sessions will be done in the morning and afternoon with at least 4 hours between sessions. Protocol consisted of a warm-up phase (5 min, 5 Hz, 250 µs), a stimulation period (30 min, 100 Hz, 400 µs, 5 s on) (0.75 s rise, 3.5 s contraction , 0.75 s fall) and 10 s off) and a cool-down phase (5 min, 5 Hz, 250 µs) The control group received no intervention.

Main outcome variables
Muscle cross-sectional area

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210712051854N7**
Registration date: **2024-06-18, 1403/03/29**
Registration timing: **registered_while_recruiting**

Last update: **2024-06-18, 1403/03/29**
Update count: **0**

Registration date
2024-06-18, 1403/03/29

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-20, 1403/02/31
Expected recruitment end date
2025-01-18, 1403/10/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Researching the efficacy of using Electrical Stimulation on the muscle changes caused by the immobility of the dominant leg due to ankle sprain

Public title
Effect of Electrical Stimulation on ankle sprains
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The study subjects are the patients who go to the emergency room of the hospital due to ankle sprain and are candidates for brace implantation.
Exclusion criteria:
BMI lower than 18.5 or higher than 30 kg/m2; Any back, knee or shoulder complaints that may interfere with the use of crutches; Type 2 diabetes determined by HBAc1 >7.0% family history of thrombosis; severe heart problems; People who have done structured and long-term resistance training during the 6 months before the study; People with neurological, muscular problems or previous trauma to any of the organs that may in any way cause a difference in the function and strength of the muscles between the left and right lower limbs of the patients.
Age
To **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is simple, in this way, we provide patients with 20 envelopes from numbers 1 to 20 so that neither the patient nor the evaluators know the order of the numbers, after the patients choose the envelopes, If the number inside the envelope is an odd number, the patient is placed in the Control group, and if the number is even, the patient is placed in the NMES 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
Research Ethics Committees of School of Medicine-Tehran University of Medical Sciences
Street address
Building no.1, Northern gate of the university, Poursina St. Qods St. Enqelab St.
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2024-03-03, 1402/12/13
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.737

Health conditions studied

1

Description of health condition studied
Dominant leg ankle sprain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Muscle cross-sectional area
Timepoint
Muscle cross-sectional area was measured at the beginning of the study (before the intervention) and 3 weeks after the intervention.
Method of measurement
Measurement of muscle cross section was done by Magnetic resonance imaging. In order to ensure consistency of measurement of each muscle, the linear distances from the lateral knee joint line to the inferior point of the lateral malleolus, as well as the linear distance from the medial knee joint line to the inferior point of the medial malleolus were measured. From these measurements, the 30 and 50% distances from the knee joint line were determined and marked with a soft-tipped marker. Prior to entering the MRI machine,

participants completed a safety screening, in the waiting room of the MRI facility fish oil tablets attached to a Velcro strap were placed at the previously measured markings of 30 and 50% of the shank length. upon completion, The fish oil tablets allowed the researchers to consistently locate the appropriate slices to measure at the correct location of the shank. A 3 Tesla magnet (TIM-Trio 3.0 T MRI, Siemens, Erlangen, Germany) was used to scan the left leg first, then the right leg. 30% shank length images were obtained first, followed by the 50% shank length image for each leg. Participants were lying supine and placed feet first into the magnet. The initial localizer scan was centered on the marked location being imaged. T1weighted MRI images were acquired using a Siemens sequence using an axial orientation, and an acquisition time of 20 s. The resolution was 1.56 mm by 1.95 mm with a slice thickness of 6 mm and a space between slices of 3 mm. The resolution matrix was 256 × 205. An8-channel knee coil was used to obtain a total of 10 images at each location. Repetition Time (TR)=7.3 ms and Echo Time (TE)=3.6 ms.

Secondary outcomes

1

Description

The muscle strength of each leg

Timepoint

The muscle strength of each leg was measured at the beginning of the study (before the intervention) and 3 weeks after the intervention.

Method of measurement

Assessment was done by hand held dynamometer . All experiments were performed with participants in the supine position with the hip and knee extended and the lower limb immobilized proximal to the ankle joint. Dynamometer against the dorsal surface of the foot just near the metatarsal heads for dorsiflexion, on the plantar surface just near the first metatarsal head for plantar flexion, on the medial side of the foot at the midpoint of the trunk of the first metatarsal for inversion, on the lateral side of the foot at the midpoint of the metatarsal The fifth was placed for eversion. To evaluate the smaller toes, the dynamometer was placed on the plantar surface of the toes. In people with smaller feet or toe deformities, there was not enough space for the device, and as a result, the smaller toes were forced to dorsiflexion. As a result, to standardize the test position, it was decided that at the maximum end range of dorsiflexion using The dynamometer should be tested for dorsiflexion of the fingers in the participant's comfortable range of motion. This technique was also used to evaluate hallux plantar flexion strength.

2

Description

Plasma glucose concentration

Timepoint

Plasma glucose concentration was measured at the beginning of the study (before the intervention).

Method of measurement

During test day 1, fasting venous blood samples will be collected to determine basal plasma glucose and insulin concentrations. Blood (10 ml) will be collected in tubes containing EDTA and directly centrifuged at 1000 g for 10 minutes at 4°C. Large amounts of plasma were immediately frozen in liquid nitrogen and stored at -80°C until further analysis. Plasma glucose concentration will be analyzed.

3

Description

Plasma insulin concentration

Timepoint

Plasma insulin concentration was measured at the beginning of the study (before the intervention).

Method of measurement

During test day 1, fasting venous blood samples will be collected to determine basal plasma glucose and insulin concentrations. Blood (10 ml) will be collected in tubes containing EDTA and directly centrifuged at 1000 g for 10 minutes at 4°C. Large amounts of plasma were immediately frozen in liquid nitrogen and stored at -80°C until further analysis. Plasma insulin concentration will also be determined.

Intervention groups

1

Description

Intervention group: For individuals assigned to the NMES group, two NMES sessions were performed every day during 3 weeks of immobility at home. For this reason, the required NMES device in pocket sizes will be available to the participants during the study period. This device will work automatically and can be manually adjusted. The initial setting of this device will be done by the study team at the beginning of the installation. Neuromuscular electrical stimulation sessions will be done in the morning and afternoon with at least 4 hours between sessions. The NMES protocol consisted of a warm-up phase (5 min, 5 Hz, 250 µs), a stimulation period (30 min, 100 Hz, 400 µs, 5 s on) (0.75 s rise, 3.5 s contraction , 0.75 s fall) and 10 s off) and a cool-down phase (5 min, 5 Hz, 250 µs).

Category

Rehabilitation

2

Description

Control group: does not receive any type of intervention.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati hospital
Full name of responsible person
Samaneh Mohammadi
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Shariati Hospital, Jalal al ahmad intersection, North Kargar street
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Tehran University of Medical Sciences
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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Latest degree
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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