

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of combination of Alphalipoic acid and neuromuscular exercises on electrical activity of affected muscles in patients with multiple sclerosis.

Protocol summary

Study aim

Evaluation of the effect of ultrasound therapy and nerve gliding techniques in patients with mild to moderate carpal tunnel syndrome

Design

Clinical trial with a control group, with parallel groups, Single blind, randomized, phase 3 on 36 patients. The block method will be used for randomization.

Settings and conduct

This study is conducted in Razi Birjand Hospital, South Khorasan Province. 36 patients are randomly divided into three intervention groups one, two and three (A-C).

Participants/Inclusion and exclusion criteria

Our study population is patients with multiple sclerosis (MS) in Birjand city under treatment with rituximab. Subjects' inclusion criteria include: age between 20 and 45 years, relapsing and relapsing MS patients with severe disease activity who are treated with rituximab, - patients with disability grade 5.4 to 6; - Patients who are able to walk without help, patients who are able to walk at least 100 meters, and the criteria for leaving the subjects include: unwillingness of patients to cooperate with the research team, absence of more than 3 sessions in training sessions, lack of regular consumption Alpha lipoic acid drug and failure to answer phone calls to continue treatment.

Intervention groups

The patients examined in the study in one of three groups including: the first group receiving alpha lipoic acid supplement for 2 months in the form of 300 mg tablets twice a day (morning and night) (A), the second group receiving exercise Neuromuscular In a period of 8 weeks (3 days a week), 18 training stations are divided in a circle including static and dynamic exercises (B) and the third group receiving supplement + neuromuscular training (C).

Main outcome variables

Average kinematic parameters of lower limb joints (three-dimensional angles of ankle, knee and thigh joints), average performance variables (timed 7.5 meters walking, rising and walking tests)

General information

Reason for update

Due to the inconsistency of the title of the trial with other parts of the study, it needed to be updated.

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043934N21**

Registration date: **2023-09-27, 1402/07/05**

Registration timing: **prospective**

Last update: **2024-10-09, 1403/07/18**

Update count: **1**

Registration date

2023-09-27, 1402/07/05

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2023-11-06, 1402/08/15 Actual recruitment start date empty Actual recruitment end date empty Trial completion date empty Scientific title The effect of combination of Alpha-lipoic acid and neuromuscular exercises on electrical activity of affected muscles in patients with multiple sclerosis. Public title The effect of alpha-lipoic acid supplementation along with neuromuscular training in the recovery of multiple sclerosis Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: Relapsing and recovering MS patients with severe disease activity who are treated with rituximab patients with disability grade 4.5 to 6 Patients who are able to walk without assistance Patients who can walk at least 100 meters Age between 20 and 45 years Exclusion criteria: Unwillingness of patients to cooperate with the research team Absence of more than 3 sessions in practice sessions Not taking alpha lipoic acid medicine regularly Failure to answer the phone call to continue the treatment Age From 20 years old to 45 years old Gender Both Phase 3 Groups that have been masked Outcome assessor Sample size Target sample size: 12 Randomization (investigator's opinion) Randomized Randomization description Placement of people in each group randomly in one of three groups including: the first group receiving alpha lipoic acid supplement for 2 months in the form of 300 mg tablets twice a day (morning and night) (A), the second group receiving The recipient of neuromuscular training in a period of 8 weeks (3 days per week) will be divided into 18 training stations in a circle including static and dynamic exercises (B) and the third group receiving supplement + neuromuscular training (C). Then, first, various triple blocks (ABC, ACB, BAC, BCA, CAB, CBA) are created on different cards. One of these blocks will be randomly selected using the lottery method and the patients will be divided into one of three groups A, B or C. Then randomization is done for other patients as well. This will be done by the secretary. Blinding (investigator's opinion)	Single blinded Blinding description Outcome evaluator: The study administrator will perform the necessary evaluation without knowing the type of intervention received by the patients and will be recorded in the checklist that was designed for this purpose. Placebo Not used Assignment Parallel Other design features Secondary Ids empty Ethics committees 1 Ethics committee Name of ethics committee Ethics Committee of Birjand University of Medical Sciences Street address Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand Town City Birjand Province South Khorasan Postal code 9717853-76 Approval date 2022-11-07, 1401/08/16 Ethics committee reference number IR.BUMS.REC.1401.307
	Health conditions studied 1 Description of health condition studied Multiple sclerosis ICD-10 code G35 ICD-10 code description Multiple sclerosis Primary outcomes 1 Description Average kinematic parameters of lower limb joints (three-dimensional angles of ankle, knee and thigh joints) Timepoint At the beginning of the study and before the start of interventions related to each group and 2 months after

the relevant interventions, a necessary evaluation is done.

Method of measurement

The IMU device is used to check the three-dimensional angles of the ankle, knee and thigh joints.

2

Description

Average performance variables (7.5 meter walking, standing and timed walking tests)

Timepoint

The IMU device is used to check the three-dimensional angles of the ankle, knee and thigh joints.

Method of measurement

To evaluate the timed rise and walk test, the time taken for a person to stand up from a normal chair with a seat height of 45 cm (leaning on the back of the chair while the soles of his feet are on the floor and behind the marking line) Get up and walk a distance of three meters at your maximum safe speed and come back and sit back on the chair and lean back. It is recorded by a stopwatch. It is also used to evaluate the 7.5 meter walking test or the 25 foot test, a standard method to check the ability of patients to walk. MS is used by neurologists in such a way that patients are asked to cover a distance of 7.5 meters as quickly as possible, which usually should be done in less than 4 seconds in healthy people and patients who do not have significant mobility disabilities.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group 1: The receiving group received alpha lipoic acid supplement in the form of 300 mg tablets twice a day (morning and night) for 2 months.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group 2: The recipient of neuromuscular training will perform 18 training stations in a circle including static and dynamic exercises in a period of 8 weeks (3 days per week).

Category

Treatment - Other

3

Description

Intervention group: Intervention group 3: receiving supplement + neuromuscular training for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Neurology Clinic of Razi Birjand Hospital

Full name of responsible person

Dr. Sadegh Mohammadnia Ahmadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Zabihullah Mohaqiq

Position

Student

Latest degree

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Other areas of specialty/work

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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