Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

The comparison of effectiveness of strengthening exercises with and without EMG-biofeedback on function in patients with muscular dystrophy

Protocol summary

Study aim
Comparison of strengthening exercise through biofeedback EMG and exercise alone on function of muscular dystrophy patients

Design
Clinical trial with control group, with two parallel groups (control and intervention), double blind (patient and assessor), randomized

Settings and conduct
Demographic information of all patients including age, sex, weight and height, medications administered, other patient interventions initially collected and muscle strength tests, patient performance tests, and balance will be assessed by the physician before intervention. In addition to the exercises training by the Physical Medicine and Rehabilitation Assistant, both groups will receive brochures on how to do the exercises correctly at home. Home exercise status will be requested through a patient checklist . After 6 weeks of intervention and after 3 months of rehabilitation program, muscle strength tests, patient performance and balance tests will be re-evaluated.

Participants/Inclusion and exclusion criteria
Inclusion criteria: proximal muscle involvement, ability to walk 10 meters alone, confirmed diagnosis of muscular dystrophy, ability to understand simple tasks Exclusion criteria: Drugs affecting muscles, acute myositis, restrictive orthopedic problem ,symptomatic cardiomyopathy

Intervention groups
Strengthening exercises are performed twice a week for 6 weeks through biofeedback, with 30-minute sessions for the intervention group and strengthening exercise alone with the occupational therapist supervision for the control group.

Main outcome variables
The Motor Function Measure-32 scale; Fatigue severity scale;Vignos Scale; Timed Up Go Test; Stair Climb Test; Stand Up from Supine Position Test; Berg Balance Scale; SF-36 for quality of life evaluation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200326046864N1**
Registration date: **2020-04-19, 1399/01/31**
Registration timing: **prospective**

Last update: **2020-04-19, 1399/01/31**
Update count: **0**

Registration date
2020-04-19, 1399/01/31

Registrant information

Name
Nastaran Maghbouli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6687 3576

Email address
nasi_lam@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2021-03-10, 1399/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of effectiveness of strengthening exercises with and without EMG-biofeedback on function in patients with muscular dystrophy

Public title
EMG-biofeedback in muscular dystrophy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Muscular dystrophy with proximal muscles involvement Approved muscular dystrophy diagnosis by neurologist Ability to walk 10 meters without help To be volunteer for intervention
Exclusion criteria:
Using drugs affecting muscular strength Acute myositis Orthopedic problems limiting patient movements Other neurologic or systemic disease involving muscles Skin lesion or infection at the site of electrode placements History of symptomatic cardiomyopathy
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
An independent researcher makes random allocation cards using computer-generated allocation table with stratification on sex and random block sizes of two and four within each stratum. He keeps the original random allocation sequences in an inaccessible third place and works with a copy. An unblinded clinical coordinator, who is not involved in testing or recruitment, will randomize subjects.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinded study personnel will consist of the principal investigator, study coordinators, outcomes assessors, and the biostatistician. Unblinded study personnel will consist of the clinical coordinator and occupational therapists delivering the intervention. Participants will only be aware that they are participating in one of two potential rehabilitation programs and will be instructed to not discuss any details of their program with any blinded personnel.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of School of Medicine- Tehran University of Medical Sciences
Street address
North Kargar
City
Tehran
Province
Tehran
Postal code
14188115516
Approval date
2019-04-27, 1398/02/07
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.031

Health conditions studied

1

Description of health condition studied
Muscular dystrophy
ICD-10 code
G71.00
ICD-10 code description
G71.00 - Muscular dystrophy, unspecified

Primary outcomes

1

Description
Muscle strength
Timepoint
before intervention, after 6 weeks intervention, 3 months post intervention
Method of measurement
dynamometer

Secondary outcomes

1

Description
Motor Function
Timepoint
before, 6 weeks and 3 months post intervention

Method of measurement
The Motor Function Measure-32 scale

2

Description
Fatigue severity
Timepoint
before, 6 weeks and 3 months post intervention
Method of measurement
Fatigue severity scale

3

Description
Balance
Timepoint
before, 6 weeks and 3 months post intervention
Method of measurement
Berg Balance Scale

4

Description
quality of life
Timepoint
before, 6 weeks and 3 months post intervention
Method of measurement
SF-36 for quality of life evaluation

Intervention groups

1

Description
Intervention group: strengthening exercises using EMG-biofeedback. EMG biofeedback is a method of retraining muscle by creating new feedback systems as a result of the conversion of myoelectrical signals in the muscle into visual and auditory signals. The program for intervention group utilizes the Loadsol® insoles (Novel.de, Munich, Germany) as real-time visual biofeedback during activity performance.The participants will do biofeedback assisted exercises for 6 weeks and 2 times a week with at least one day interval. Each session will take about 30-40 minutes.Exercises provided on the flexor, abductor and adductor muscles of the hip and knee flexors and extensors. The participants will be assessed for retention of motor learning from the previous session on their current activities to determine if they are ready for intervention progression. The frequency of biofeedback will be faded to 50% using an intermittent biofeedback schedule along with random practice of the activities to promote retention of the improved movement pattern. The INTERVENTION group home exercise program will be the same as the CONTROL group home exercise program focusing on 10 strengthening and balance improving exercises.
Category
Rehabilitation

2

Description
Control group: strengthening exercises with occupational therapist supervision, Participants enrolled in the CONTROL program will focus on the same exercise protocol as the intervention program, though the treating occupational therapist will not provide any instructed feedback on movement patterns during their treatment beyond minimal cues for safety. Progression within activities in the CONTROL group will be based upon the participant's tolerance and safety in performing the activity. The CONTROL home exercise program will be the same as the intervention group but without use of biofeedback.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati hospital- Tehran University of medical sciences
Full name of responsible person
Nastaran Maghbouli
Street address
No. 25, Jalal Al-Ahmad Highway, North Kargar Street, Tehran
City
Tehran
Province
Tehran
Postal code
1418815516
Phone
+98 21 8490 2110
Email
nasi_lam@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hamidreza Fateh
Street address
No. 25, Jalal Al-Ahmad Highway, North Kargar Street, Tehran
City
Tehran
Province
Tehran
Postal code
1418815516
Phone
+98 21 8490 2110

Email
hr.fateh@gmail.com
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
Tehran University of Medical Sciences
Full name of responsible person
Nastaran Maghbouli
Position
Clinical resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
No. 25, Jalal Al-Ahmad Highway, North Kargar Street, Tehran
City
Tehran
Province
Tehran
Postal code
1418815516
Phone
+98 21 8490 2110
Email
nasi_lam@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Nastaran Maghbouli
Position
Clinical resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
No. 25, Jalal Al-Ahmad Highway, North Kargar Street, Tehran
City
Tehran
Province
Tehran
Postal code
1418815516
Phone
+98 21 8490 2110
Email
nasi_lam@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Nastaran Maghbouli
Position
clinical resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
No. 25, Jalal Al-Ahmad Highway, North Kargar Street, Tehran
City
Tehran
Province
Tehran
Postal code
1418815516
Phone
+98 21 8490 2110
Email
nasi_lam@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The findings of this study will be published as soon as possible.
When the data will become available and for how long

2022

To whom data/document is available

results will be available for journals readers data will be available for reasonable requests for example systematic reviews

Under which criteria data/document could be used

systematic review and meta analysis

From where data/document is obtainable

Shariati Hospital, Tehran, Rehabilitation Department

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

Through email: nasi_lam@yahoo.com

Comments