Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The comparison of physiotherapy by parents at home and physiotherapy by expert physiotherapist in patients with Duchenne muscular dystrophy: Randomized controlled trial

Protocol summary

Study aim

The comparison between physiotherapy at home and physiotherapy by expert physiotherapist in patients with Duchenne Muscular Dystrophy

Design

the randomized Clinical trials with control group, with parallel groups. The sample size was calculated 50

Settings and conduct

All children with Duchenne Muscular Dystrophy who are referred to the Neurology Clinic or Faculty of Physics or the Department of Physical Therapy at the Children's Medical Center, who approved by a specialist physician. Patients will randomly divided into two groups. The first group of physiotherapy at home is trained by the fellows and the second group will be physiotherapy by a qualified physiotherapist. In both groups, a bi-weekly physiotherapy will be conducted. The parameters evaluated will be evaluated in two groups in both laboratory and clinical categories. The clinical parameters assessed include muscle pain, number of muscle cramps per week, muscle weakness in four limbs that had upper limb based on the international brooke and limb The bottom line will be reviewed based on the NSAA benchmark. Also, the severity of muscle atrophy will be classified according to clinical judgment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with clinical and Duchenne muscular dystrophy biopsy diagnosis, residence in the northwest of the country, having a higher literacy level and age range 18 to 50 years, informed consent of parents for participation in the study. Exclusion criteria: lack of housing or relocation of the North West of the country, lack of informed consent to participate or continue the study, lack of education or poor cooperation .

Intervention groups

patients with Duchenne Muscular Dystrophy

Main outcome variables

The amount of muscle pain changes The rate of change in muscle cramp The rate of muscle weakness Severity of muscle atrophy

General information

Reason for update

Acronym

DMD: Duchenne muscular dystrophy ROM: Range of Motion NSSA: the north star ambulatory assessment

IRCT registration information

IRCT registration number: **IRCT20131012014988N7**
Registration date: **2019-07-02, 1398/04/11**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-02, 1398/04/11**
Update count: **0**

Registration date

2019-07-02, 1398/04/11

Registrant information

Name

Mohammad Barzegar

Name of organization / entity

Pediatric Health Research Center,Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3526 2265

Email address

phrc_mb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of physiotherapy by parents at home and physiotherapy by expert physiotherapist in patients with Duchenne muscular dystrophy: Randomized controlled trial

Public title

The Effectiveness of Physical Therapy at Home in Patients with Duchenne Muscular Dystrophy

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Duchenne muscular dystrophy who their clinical illness was confirmed by Biopsy and genetic test . alert parents between 18-50 years old informed consent live in north western in Iran

Exclusion criteria:

Patients that they dont live in North western of Iran or they Migrate No informed consent for participation or continuation of the study, they dont want to take part or don't have enough education.

Age

To **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization to divide patients into two groups by simple randomization method individually Accidental randomization was done based on random selection software Patients were coded and randomly divided into two groups

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

We will divide patients into two groups randomly, the first group receive physiotherapy two times per week with expert physiotherapist. The second group's parents will train by the same physiotherapist to do that at home with the same method. after 6 month followup we compare their muscle force scores and muscle cramps per week and muscle atrophy.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht Ave, medicine faculty

City

Tabriz

Province

East Azarbaijan

Postal code

5157610144

Approval date

2019-04-09, 1398/01/20

Ethics committee reference number

IR.TBZMED.REC.1398.011

Health conditions studied

1

Description of health condition studied

Duchenne Muscular Dystrophy

ICD-10 code

G71.0

ICD-10 code description

Muscular dystrophy

Primary outcomes

1

Description

Musculoskeletal pain (based on scores ranging from 0 to 10), the frequency of muscle cramps per week, muscle weakness in the four limbs with upper limb based on the international brooke score (1 to 6) and lower limbs based on the NSAA score (1 to 34 with 17 items)

Timepoint

These parameters will be evaluated 2 times, 1- before the treatment and 2- six months after the treatment

Method of measurement

The upper limb muscle weakness score with the Brooke system and the lower muscle weakness score will be scored based on the NSAA system. The North Star Ambulatory Assessment (NSAA) has 17 items that can be used to assess motor ability in pediatric patients with duodenal muscular dystrophy. The highest score in this system is scoring 34, which means the ability to move completely independently. Brooke's Benchmarking

Questionnaire uses 10 questions to evaluate muscular ability in the upper limb of patients with Duchenne's muscular dystrophy.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Teaching Physical Therapy at Home to Parents or Patients - Physical Therapy At Home
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Children's Hospital
Full name of responsible person
Mohammad Barzegar
Street address
Sheshgelan Ave, Tabriz Children's Hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5154300633
Phone
+98 41 3337 2084
Email
phrc_mb@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Barzegar
Street address
Sheshgelan Ave, Tabriz children's hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5154300633
Phone
+98 41 3337 2084
Email
phrc_mb@tbzmed.az.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Barzegar
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Sheshgelan Ave, Tabriz children's hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5154300633
Phone
+98 41 3337 2084
Email
phrc_mb@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Barzegar
Position
Professor,
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Shasghelan Ave, Tabriz Children's Hospital
City
Tabriz

Province
East Azarbaijan
Postal code
5154300633
Phone
+98 41333372084
Email
phrc_mb@tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Barzegar
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Shasghelan Ave, Tabriz Children's Hospital
City
Tabriz
Province
East Azarbaijan
Postal code
5154300633
Phone
+98 41 3337 2084
Email
phrc_mb@tbzmed.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Only a portion of the information, such as the original outcome information, will be shared
When the data will become available and for how long
data from this study will be available, six months after the publication of this study,
To whom data/document is available
All who apply
Under which criteria data/document could be used
There are no specific requirements to apply
From where data/document is obtainable
correspond : Mohammad Barzegar
phrc_mb@tbzmed.ac.ir
What processes are involved for a request to access data/document
email to correspond author
Comments