

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of safety and efficacy of autologous adipose-derived mesenchymal cells therapy in Duchenne muscular dystrophy patients

Protocol summary

Study aim

Evaluation of therapeutic effects and complications of treatment of Duchenne muscular dystrophy with stem cells

Design

The clinical trial is performed on 10 patients who have referred for treatment and are followed up for one year.

Settings and conduct

After 300 to 600 cc of subcutaneous adipose tissue is extracted from the patient's abdomen and 100 to 150 cc of SVF is prepared, the resulting product is injected intravenously into the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 7 to 30 years old; genetic evidence; the patient's ability to walk is not completely lost and the use of assistive devices is not permanent; the patient's muscle strength is decreasing; willingness and satisfaction to participate in the study. Exclusion criteria: advanced motor impairment leading to permanent use of crutches, walkers and wheelchairs; history of known malignancy; history of associated genetic and non-genetic degenerative diseases; having blood and internal diseases that increase the risk of liposuction and anesthesia required; history of any other acute or chronic illness that, at the discretion of the clinician responsible for implementing the plan, prevents the patient from entering the study; insufficient volume of subcutaneous fat or the presence of concomitant injuries in the abdomen.

Intervention groups

100 to 150 cc of SVF product containing 20% mesenchymal cells, 60% progenitor cells and 20% other autologous cells in albumin medium will be injected intravenously through peripheral vein once in 10 to 30 minutes.

Main outcome variables

Respiratory Function(FVC); Muscular Function(physical examination and lab study); Cardiac Function(EF)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150206020981N3**

Registration date: **2022-06-07, 1401/03/17**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-07, 1401/03/17**

Update count: **0**

Registration date

2022-06-07, 1401/03/17

Registrant information

Name

Khadijeh Hajinaghitehrani

Name of organization / entity

Azad Medical University

Country

Iran (Islamic Republic of)

Phone

+98 21 2257 1228

Email address

khtehrani@iautmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-31, 1401/03/10

Expected recruitment end date

2023-05-31, 1402/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and efficacy of autologous adipose-derived mesenchymal cells therapy in Duchenne muscular dystrophy patients

Public title

Efficacy of autologous adipose tissue-derived mesenchymal stem cell therapy in Duchenne muscular dystrophic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Genetic evidence of Duchenne disease as a cause of myopathy The patient's ability to walk is not completely lost and the use of assistive devices such as canes and walkers is not permanent. The patient's muscle strength is decreasing Willingness and satisfaction to participate in the study by the patient's legal guardian in decision making and willingness to participate regularly in follow-up courses

Exclusion criteria:

Advanced motor impairment leading to permanent use of crutches, walkers and wheelchairs A history of known malignancy History of associated genetic and non-genetic degenerative diseases Having blood and internal diseases that increase the risk of liposuction and anesthesia required A history of any other acute or chronic illness that, at the discretion of the clinician responsible for implementing the plan, prevents the patient from entering the study. Insufficient volume of subcutaneous fat or the presence of concomitant injuries in the abdomen in the initial examination that make it difficult to obtain adipose tissue to prepare SVF.

Age

From **7 years** old to **30 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee on Research Islamic Azad University, Tehran Medical Branch

Street address

Attari Moghadam Ave, Khaghani Ave, Shariati Ave, Islamic Azad University, Tehran Medical Branch

City

Tehran

Province

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Postal code

1936893813

Approval date

2022-04-26, 1401/02/06

Ethics committee reference number

IR.IAU.TMU.REC.1401.038

Health conditions studied

1

Description of health condition studied

Duchenne muscular dystrophy

ICD-10 code

G71.01

ICD-10 code description

Muscular dystrophy

Primary outcomes

1

Description

Respiratory Function

Timepoint

1, 3, 6, 9 and 12 month after injection

Method of measurement

Spirometry

2

Description

Muscular Force

Timepoint

First every 14 days to 1 month, then Every 1 month to 1 year

Method of measurement

Physical Exam

3

Description

Cardiac Function

Timepoint

1, 3, 6, 9 and 12 month after injection

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Muscular Enzymes

Timepoint

1, 3, 6, 9 and 12 month after injection

Method of measurement

Lab Data

Intervention groups

1

Description

Intervention group: 100 to 150 cc of SVF product containing 20% mesenchymal cells, 60% progenitor cells and 20% other autologous cells in albumin medium will be injected intravenously through peripheral vein once in 10 to 30 minutes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Muscular Dystrophy Association

Full name of responsible person

Dr. Khadijeh Hajinaghi Tehrani

Street address

No 27, Montazeri St. Piroozi St. Shohada Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Islamic Azad University, Tehran Medical Branch

Full name of responsible person

Farshad Hashemian

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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

Research Deputy of Islamic Azad University, Tehran Medical Branch

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

Bu-ali Hospital

Full name of responsible person

Khadijeh Hajinaghi Tehrani

Position

Neurologist

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Neurologist

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

The only some part of data will be shared.

When the data will become available and for how long

5 months after publish

To whom data/document is available

Only academic researcher

Under which criteria data/document could be used

By official permission

From where data/document is obtainable

By the corresponding author

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

By the official request to the corresponding author, if she/he agrees to it.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Farhikhtegan Hospital

Full name of responsible person

Fatemeh Naseri Atashani

Position

MD

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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