

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Autologous bone marrow derived mononuclear cells (BMMNCs) subfacial transplantation in idiopathic lymphedema patients: clinical trial phase I

Protocol summary

Summary

Objectives: safety assessments of subfacial transplantation of autologous bone marrow derived mononuclear cells (BMMNCs) in idiopathic lymphedema patients. Design: A Phase I, Multicenter, Un-Controlled, Non-Randomized, Open label Clinical Trial. Methods: 6 patients with Idiopathic lower limb lymphedema; age between 10-35 years; Grade less than III; Resistant to conventional therapy and both gender selected. They underwent bone marrow aspiration. The prepared autologous bone marrow derived mononuclear cells inject subfascially during lymph pathway in involved leg. They follow at 1,2,3,6 and 12 months after transplantation by clinical assessments Questionnaire, Water displacement leg volumetry and circumference measurement. The primary endpoint was assessed by clinical assessment of safety including redness, swelling, itching, inflammation, infection, reduced sensitivity and etc.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611241031N19**
Registration date: **2017-01-27, 1395/11/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-27, 1395/11/08

Registrant information

Name

Nasser Aghdami

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2000

Email address

nasser.aghdami@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Department of Regenerative Biomedicine, Cell Science Research Center, Royan Institute for Stem Cell Biology and Technology, ACECR.

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Autologous bone marrow derived mononuclear cells (BMMNCs) subfacial transplantation in idiopathic lymphedema patients: clinical trial phase I

Public title

Autologous bone marrow derived mononuclear cells transplantation in idiopathic lower limb lymphedema patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 10-35 years; Idiopathic lower limb lymphedema; Grade less than III ; Resistant to conventional therapy; Informed consent. Exclusion criteria: Heart Failure (EF less than 45%); Renal failure (Cr more than 2) ; Hepatic failure (LFT more than 3

times) ; History of related surgery (lymph node dissection); History of Autoimmune disease; History of trauma or infection; History of pelvic malignancy or treatment for malignancy (Irradiation); Symptoms of sleep apnea; Previous bone marrow transplant; Morbid obesity or Lipedema (BMI $\geq$ 40); Allergic disorders; Cytotoxic drugs; Drugs induced lymphedema; Congenital vascular malformation; Myxedema; Traveling to tropical countries or suspicion to filariasis; Dependency.

Age

From **10 years** old to **35 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **6**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

not used

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethic and Law Research Center, Shahid Beheshti University of Medical Sciences

Street address

Velenjak Street, Shahid Chamran Highway

City

Tehran

Postal code

1985717443

Approval date

2014-02-09, 1392/11/20

Ethics committee reference number

SBMU.REC.1392.656

Health conditions studied

1

Description of health condition studied

Idiopathic lower limb lymphedema

ICD-10 code

I89.9

ICD-10 code description

Noninfective disorder of lymphatic vessels and lymph nodes, unspecified

Primary outcomes

1

Description

Safety

Timepoint

Base, 1,2,3,6 and 12 months after transplantation

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Edema volume

Timepoint

base, 1,2,3,6 and 12 months after transplantation

Method of measurement

Water displacement leg volumetry, Circumference measurement

2

Description

SF-36 Health Status Questionnaire

Timepoint

6 and 12 months after transplantation

Method of measurement

Questionnaire

Intervention groups

1

Description

Sub-facial transplantation of autologous bone marrow derived mononuclear cell. 0.5-1 cc per point injection. number of point injection is one third of leg length plus 1. cell suspension is half of number of point injections in involved leg

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada e Tajrish Hospital

Full name of responsible person

Dr. Seyed Reza Moosavi

Street address

Tajrish Sq.
City
Tehran

Country of origin
Type of organization providing the funding
empty

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Hamid Gourabi

Street address

Eastern Hafez St, Northern Banihashem St, 45 m
Resalat highway

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Royan Institute

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Aliasghar Peyvandi

Street address

Shahid Beheshti University of Medical Science,
Velenjak St. Chamran Highway

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Science

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Hoda Madani

Position

M.D/Researcher

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty