

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Investigating the Effects of Peripheral Blood Stem Cells Injection in Treatment of Primary Lower Extremity Lymphedema

Protocol summary

Study aim

The aim of this pilot before and after single arm clinical trial is the cure of lymphedema via induction of lymphangiogenesis by autologous peripheral blood stem cells injection to the unilateral lymphedematous lower extremity. To reach this goal, improvements will be tracked histopathologically (average number of lymphatic vessels via biopsy), by imaging (lymphoscintigraphy), clinically (stage of lymphedema and measurement of circumference and volume of the limb) and via patients' sense of wellness (quality of life). The other goals are assessment the relation between these variables and the age, duration and severity of disease.

Design

A pilot before and after single arm clinical trial with a single group of 10 patients

Settings and conduct

This study will be totally taking place in Shariati Hospital of the Tehran University of Medical Science, Tehran, Iran. The recruitment and follow up center is the hospital's vascular surgery clinic, the cell preparations will be proceeded in the hospital's Hematology, Oncology and Stem Cell Transplantation Research Center and the stem cells will be injected in the hospital's operation room. The experts of the hospital's pathology lab and nuclear medicine imaging center will do the histopathologic investigation and lymphoscintigraphy. The main investigators may be keep blinded from the primary histopathologic and lymphoscintigraphic data (except the presence of lymphedema).

Participants/Inclusion and exclusion criteria

Patients with lower extremity/ies primary lymphedema will be recruited and among them, patients with history of malignancy or radio/chemotherapy or organ transplantation in the last 10 years and coronary artery disease, severe heart failure (EF<30%), chronic renal disease, diabetes and uncontrolled hypertension and active infection in the lower extremity will be excluded.

Intervention groups

The intervention is including 3-5 days of subcutaneously injection of GCSF for stem cell recruitment from bone marrow into the peripheral blood and then drawing blood from peripheral vessels to separate the peripheral blood stem cells. After cell preparations, half of the cells will be injected subcutaneously into the unilateral lymphedematous lower limb in about 80 points and the other half of the cells will be frozen for the similar injection 3 weeks later. Also, a punch biology for histopathologic investigation and lymphoscintigraphy will be obtained before the intervention and at the end of the 9 months of follow up. Patients will fill the Quality of Life questionnaire before the intervention and after the 9 months of follow up. The essential variable is the circumference and volume of the limb which will be measured monthly for 9 months.

Main outcome variables

Circumference and volume of the lower extremity, lymphoscintigraphic transport index, average number of subcutaneous lymphatic vessels and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171023036966N1**

Registration date: **2018-01-22, 1396/11/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-22, 1396/11/02**

Update count: **0**

Registration date

2018-01-22, 1396/11/02

Registrant information

Name

Vida Ehyae Ghodraty

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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+98 21 6443 2592

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-19, 1396/10/29

Expected recruitment end date

2019-01-19, 1397/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effects of Peripheral Blood Stem Cells Injection in Treatment of Primary Lower Extremity Lymphedema

Public title

Using the Stem Cells to Cure Lower Limb Lymphedema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

primary lower extremities lymphedema (stage < III)

Exclusion criteria:

Uncontrolled hypertension Diabetes Sever heart failure (EF<30 %) Coronary arterial disease Chronic renal disease History of any malignancies over the last 10 years History of chemo/radiotherapy in the last 10 years Organ transplantations in the last 10 years Active infection of the lower extremities

Age

No age limit

Gender

Both

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

Research Ethics committee of Tehran University of Medical Science

Street address

Office #605, 6th floor, core building of Tehran University of Medical Science, cross section of Ghods street and Keshavarz blv.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2017-07-25, 1396/05/03

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.2984

Health conditions studied

1

Description of health condition studied

Lymphedema is the accumulation of lymphatic fluid in the extravascular space resulted from dysfunction of lymphatic drainage because of mostly structural damage in lymphatic vessels. Various etiology of lymphedema is consist of primary and genetic malfunctions presenting the disease congenitally, over the first year after birth, up to 35 years or after this age and cancers and their treatment methods, traumas and other causes for example filariasis can cause the secondary lymphedema which is more common. Once lymphedema occurs it may be progressive with different rates and transform the involving limb and this causes pain, movement limitations and makes the limb prone to infections. There are various methods of management but not curative like compression therapies and surgical methods.

ICD-10 code

I89.0

ICD-10 code description

Lymphedema, not elsewhere classified

2

Description of health condition studied

Hereditary lymphedema is the primary lymphedema in which genetically malfunctional lymphatic vessels rather than obstructions or destructions via cancer, trauma and etc. lead to lymphatic drainage dysfunction and lymphedema.

ICD-10 code

Q82.0

ICD-10 code description

Hereditary lymphedema

Primary outcomes**1****Description**

Circumference of the lymphedematous lower extremity in specific distances of the limb length

Timepoint

Before intervention and then monthly up to 9 months

Method of measurement

Tape measuring

2**Description**

Volume of the Circumference of the lymphedematous lower extremity

Timepoint

Before intervention and then monthly up to 9 months

Method of measurement

Volume of truncated cone formula

Secondary outcomes**1****Description**

Quality of life

Timepoint

Before intervention and end of the follow up time (9 months after intervention)

Method of measurement

WHO QOL questionnaire (SF 26)

2**Description**

Lymphoscintigraphic Transport Index (TI)

Timepoint

Before intervention and end of the follow up time (9 months after intervention)

Method of measurement

Report of lymphoscintigraphy by the expert nuclear medicine specialist

3**Description**

Average number of subcutaneous lymphatic vessels of the lower extremities

Timepoint

Before intervention and end of the follow up time (9 months after intervention)

Method of measurement

Histopathologic investigation and immunohistochemistry (IHC) staining by the expert pathologist

Intervention groups**1****Description**

Intervention group: a single group of 10 patients with primary lower extremity(ies) lymphedema, with no exclusion criteria, will receive 10mcg/kg/day of G-CSF for 3-5 days to recruit more stem cells from bone marrow to peripheral blood. Stem cells will be separated from 200-300 cc of peripheral blood drawn from the cubital vein. Half of the cells will be injected subcutaneously to 80-100 points of unilateral limb and the other half will be frozen for a second injection, 3 weeks later. The circumference and volume of the limb (monthly), the average number of lymphatic vessels (via biopsy), severity of lymphedema (lymphoscintigraphy and transport index), and the quality of life (questionnaire) will be compared before and after the 9 months past the intervention.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinic of Vascular Surgery in Shariati Hospital

Full name of responsible person

Behnam Molavi

Street address

North Kargar street, Shariati Hospital

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Tehran

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1411713135

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Email

molavibe@sina.tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hematology, Oncology and Stem Cell Transplantation Research Center

Full name of responsible person

Saeed Mohammadi

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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

Hematology, Oncology and Stem Cell Transplantation
Research Center

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

Department of Vascular Surgery, Shariati Hospital

Full name of responsible person

Behnam Molavi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Vascular and Endovascular surgery

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inquiries

Contact

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Department of Vascular Surgery, Shariati Hospital

Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Shariati Hospital

Full name of responsible person

Vida Ehyae Ghodraty

Position

Physician in practice

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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

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

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All the deidentified measurements from the participants including medical history and data of size of the limb, lymphoscintigraphic and histopathologic procedures and data before and after the intervention and also the detailed cellular preparations procedures will be available for other researchers.

When the data will become available and for how long

It can become available just after finding a dramatic result or at the end of the study for an unlimited time.

To whom data/document is available

All the information will be available for research ethic committees, detailed procedures and statistics can be available for researchers and the results and summary of procedures can be useful for industries and lymphedematous patients.

Under which criteria data/document could be used

Not specific criteria.

From where data/document is obtainable

During the study, please contact the project e-mail: lymphedema.research.tums@gmail.com After publishing the article there will be a guide for obtaining it.

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

Contact with project email and send your request. lymphedema.research.tums@gmail.com

Comments

lymphedema.research.tums@gmail.com