Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Autologous Adult Stem Cell Induced-Lymphangiogenesis in Peripheral Lymphedema

Protocol summary

Summary

There are no Effective Therapeutic Interventions for Lymphatic Vessels Disease. The efficacy of some Methods like Physical Combined Therapy Demands more time and money with lower Effectiveness. Inclusion Criteria are Congenital Atresia or Hypoplasia of Lymphatic Vessels and Exclusion Criteria are any Inflammatory or Malignant Disease. Research Study is carried out on 5 Samples from Human Population. It seems Injection of Stem Cells in Edema Region can Stimulate Cytokine Excretion and Finally Improve Function of Endothelial Cells of Lymphatic Vessels or making new Lymphatic Systems. For every Patient Recombinant Granulocyte Colony-Stimulating Factor (5 Microgram per Kilogram of Body Weight) is Injected Subcutaneously for 5 days long. At this period, Stem Cells (Endothelial Precursors) are Recruited from Bone Marrow to Peripheral Blood. Daily White Cell Count is done until we reach Desirable Mononuclear Count and then they will be Collected from Peripheral Blood. Then this Solution which contains Mononuclear Cells, will be Concentrated and Final Volume of Solution will be 120 cc. this Solution will be then Injected in Sterile Method in Anatomic Pathway of Lymphatic Vessels of Lower Limb, from left Groin to Distal part of left Shinbone. Percentage of CD34+/CD133+ Cells will be measured before Injection by flow Cytometry Method. Several Tests will be done on Patient after Injection of Autolog Stem Cells, to Assay Clinical and Lymphoscintigraphy Findings. These Parameters will be Compared to data before Intervention. 40 days after Stem Cells Injection, Probably Diameter of lower Limb will be Reduced Significantly in Comparison to Pre Intervention Diameter.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202209083N1**

Registration date: **2012-03-12, 1390/12/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-12, 1390/12/22

Registrant information

Name

Habiballah Peirovi

Name of organization / entity

nanomedicine&tissue engineering research center-shahid behesht medical university

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 9848

Email address

dhpsurgery@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences, Stem Cell

Expected recruitment start date

2012-02-20, 1390/12/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Autologous Adult Stem Cell Induced-Lymphangiogenesis in Peripheral Lymphedema

Public title
Autologous Adult Stem Cell Induced-Lymphangiogenesis in Peripheral Lymphedema
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion:/ Congential Atresia or Hypoplasia of Lymphatic Vesseles Exclusion Criteria :/Inflamatory Malignant Disease
Age
From **16 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **5**
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
Shahid Beheshti of Medical University
Street address
Nano, Taleghani Hospital, Velenjak, Shahid Beheshti of Medical University
City
Tehran
Postal code
198571-7413
Approval date
2012-01-29, 1390/11/09
Ethics committee reference number
112

Health conditions studied

1

Description of health condition studied
Lymphoedema
ICD-10 code
I89.0
ICD-10 code description
Lymphoedema, not elsewhere classified

Primary outcomes

1

Description
Diametr of Organ
Timepoint
15 day, 1 m, 3m, 6m, 12m
Method of measurement
Centimeter

2

Description
Lymphosentigraphy
Timepoint
15 day, 1 m, 3m, 6m, 12m
Method of measurement
Lymphosentigraphy

Secondary outcomes

empty

Intervention groups

1

Description
1) Bone Marrow Aspiration 2) Detachment Precursur Cell Endothelial with CLINIMACS Cell Sẽparator System 3) Cell Culture 4) Injection Subcutanens in Local Specific
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital,
Full name of responsible person
Dr Habib Allah Peirovi
Street address
Taleghani Hospital, Velenjak,
City
Thran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Staff of Stemcell ,By Shahid Beheshti of Medical University
Full name of responsible person

Dr Mohammad Vaseii

Street address

Room 304, Floor 3, Adjutancy of Research Department, Avesta Park, Aazadi

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Staff of Stemcell ,By Shahid Beheshti of Medical University

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

Nano Medicine& Tissue Engineering Research Center (Shahid Beheshti of Medical University)

Full name of responsible person

Dr Habib Allah Peirovi

Position

Proff of General & Vascular Surgery(Head of Center)

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Habib Allah Peirovi

Position

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Contact

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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