

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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:/ Congenital 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 Precursor Cell  
Endothelial with CLINIMACS Cell Sêparator 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**

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

**City**

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1985717413

**Phone**

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dhpsurgery@sbmu.ac.ir

**Web page address**

<http://www.sbmu.ac.ir/SiteDirectory/NMTERC/default.aspx>

## Person responsible for scientific 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 )

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## Person responsible for updating data

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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*