

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Investigation on autologous mesenchymal stem cell transplantation in diabetic neuropathy

Protocol summary

Summary

In the first through volunteers patients with diabetes type 1 ,that they have diabetic neuropathy and to take the similar medication in the two groups control and case consisted of twenty patients in each group will be selected. The plan is explained for all patients after if they want to be entered in study they have to sign consent. Then the patient is asked to monitor their blood glucose for one month (Self Monitoring Blood Glucose) should be to control their diabetes. After each patient are sampled to measure fasting blood glucose and HbA1C in Laboratory of Diabetes Centerpy. Adult human MSCs are isolated from the healthy bone marrow of patients of case group and cultured. Patients receive 1 injection dose of 2 million MSCs/kg. patients.Both of two groups one week before cell therapy and 1.5 ,3 , 6,12 and months after cell therapy will be examined by the medical team that includes physicians, endocrinology and neurological .Michigan survey, UK, a ten-point test monofilament test , diapason ,,(VASVisual Analog Scale) test and EMG NCV will be performed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103171414N23**

Registration date: **2012-07-10, 1391/04/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-10, 1391/04/20

Registrant information

Name

Bagher Larijani

Name of organization / entity

Endocrinology & Metabolism Research Center, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8822 0037

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emrc@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Endocrinology and Metabolism Research Institute Tehran
University Of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation on autologous mesenchymal stem cell
transplantation in diabetic neuropathy

Public title

Effect of mesenchymal stem cells transplantation to
improve of diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-People with diabetes type one that
their disease passed at least 10 years 2-signing informed
consent, 3-age 40-60 years 4- All patients are eligible for
cell therapy (under protocol) 5 - HbA1c $\leq$ 7.5% (blood
glucose is controlled at least of one month) 6 - BP $\leq$

130/80 Exclusion criteria: 1 - acute inflammation of vascular 2 - acute thrombosis (three months) 3 - recent bleeding in the retina (the last three months) 4 - pulmonary hypertension 5 - liver disease 6- tumors in bone marrow or any malignancy is diagnosed 7 - infectious diseases 8-mental illness 9- generalized edema 10 - malignancy 11 - pregnancy 12 - to use any walking aids 13 - having a foot ulcer during the study 14 - amputation of limbs

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Tehran University Of Medical Sciences

Street address

5th floor, Dr.Shariati hospital, North Kargar avenue,

City

Tehran

Postal code

1411413137

Approval date

2011-12-28, 1390/10/07

Ethics committee reference number

E-00182

Health conditions studied

1

Description of health condition studied

Diabetic neuropathy

ICD-10 code

G63.2*

ICD-10 code description

Diabetic polyneuropathy (E10-E14 with common fourth character .4+)

Primary outcomes

1

Description

Monofilament test

Timepoint

Before intervention and 6,12,24,48,96 weeks after intervention

Method of measurement

Numeration

2

Description

Diapason test

Timepoint

Before intervention and 6,12,24,48,96 weeks after intervention

Method of measurement

Numeration

3

Description

Electromyography & Nerve conduction velocity

Timepoint

Before intervention and 6,12,24,48,96 weeks after intervention

Method of measurement

mV

4

Description

Visual Analog Scale

Timepoint

Before intervention and 6,12,24,48,96 weeks after intervention

Method of measurement

numerical

Secondary outcomes

1

Description

Weight

Timepoint

Before intervention and 4,12,24,48,96 weeks after intervention

Method of measurement

Weigher

2

Description

Fasting blood glucose
Timepoint
Before intervention and 4,12,24,48,96 weeks after intervention
Method of measurement
Glucose oxidase

3

Description
HbA1c
Timepoint
Before intervention and 4,12,24,48,96 weeks after intervention
Method of measurement
HPLC

Intervention groups

1

Description
Once Injection 2 million cells per kilogram of body weight of autologous mesenchymal stem cells were taken from the bone marrow amount of 50 ml during 30 minutes for one time.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology & Metabolism Research Institute
Tehran University Of Medical Sciences
Full name of responsible person
Dr. Ensieh Nasli
Street address
5th floor, Dr.Shariati hospital, North Kargar avenue,
Tehran, Iran
City
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2

Recruitment center
Name of recruitment center
Endocrinology & Metabolism Research Institute
Tehran University Of Medical Sciences
Full name of responsible person
Dr. Nika Mojahed
Street address
5th floor, Dr.Shariati hospital, North Kargar avenue
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Endocrinology & Metabolism Research Institute
Tehran University Of Medical Sciences
Full name of responsible person
Dr. Ramin Heshmat
Street address
5th floor, Dr.Shariati hospital, North Kargar avenue,
Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Endocrinology & Metabolism Research Institute Tehran
University Of Medical Sciences
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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Endocrinology & Metabolism Research InstituteTehran
University Of Medical Sciences
Full name of responsible person
Dr. Bagher Larijani
Position
Professor
Other areas of specialty/work
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Person responsible for updating data

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Endocrinology & Metabolism Research Institute
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Dr. Ensieh Nasli -

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Assistant professor

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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