Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation on autologous mesenchymal stem cell transplantation in diabetic neurophaty

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 Glocose) 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)

Phone

+98 21 8822 0037

Email address

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 neurophaty

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 years4- All patients are eligible for cell therapy (under protocol) 5 - HbA1c ≤ 7.5% (blood glucose is controlled at least of one month) 6 - BP ≤

130/80Exclusion 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 neurophaty

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 & Nnerve 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

Tehran

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

Street address

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

City

Tehran

Postal code

1411413137

Phone

+98 21 8822 0037

Fax

+98 21 8822 0052

Email

emrc@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Endocrinology & Metabolism Research InstituteTehran University Of Medical Sciences

Full name of responsible person
Dr. Ensieh Nasli -

Position
Assistant professor

Other areas of specialty/work

Street address
5th floor, Dr.Shariati hospital, North Kargar avenue, Tehran, Iran

City
Tehran

Postal code
1411413137

Phone
+98 21 8490 2677

Fax
+98 21 8822 0052

Email
emrc@tums.ac.ir

Web page address

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