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A Clinical Study Using Adipose-derived Stem Cells for Diabetic Foot

This study is currently recruiting participants.

See Contacts and Locations

Verified April 2017 by Jie Shen, The Third Affiliated Hospital of Southern Medical University

Sponsor:

Jie Shen

ClinicalTrials.gov Identifier:

NCT02831075

First Posted: July 13, 2016

Last Update Posted: April 7, 2017

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our <u>disclaimer</u> for details.

Collaborators:

Nanfang Hospital of Southern Medical University

Academy Military Medical Science, China

The Fifth Affiliated Hospital of Southern Medical University

Southern Medical University, China

Information provided by (Responsible Party):

Jie Shen, The Third Affiliated Hospital of Southern Medical University

Full Text View

Tabular View

No Study Results Posted

Disclaimer

How to Read a Study Record



establish an optimal clinical research program, and attempts to break the technical bottleneck in the stem cell therapy for treating diabetes related vascular complications.

Condition	Intervention	Phase
Peripheral Vascular Disease	Biological: Adipose-derived stem cell	Phase 1
Ischemia	Biological: saline	
Diabetic Foot		

Study Type: Interventional

Study Design: Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: None (Open Label)
Primary Purpose: Treatment

Official Title: A Clinical Study Using Adipose-derived Stem Cells for Diabetic Foot

Resource links provided by NLM:

MedlinePlus related topics: Diabetic Foot Foot Health

U.S. FDA Resources

Further study details as provided by Jie Shen, The Third Affiliated Hospital of Southern Medical University:

Primary Outcome Measures:

• Area of diabetic foot ulcers [Time Frame: 3 months]

To determine the ability of MSC to facilitate and accelerate diabetic foot ulcers healing.

Secondary Outcome Measures:

- Improvement of transcutaneous oxygen partial pressure (TcPO2) [Time Frame: 3 months]
 Improvement of local perfusion.
- Improvement of microvascular cutaneous reactivity by laser Doppler perfusion monitoring (LDPM) [Time Frame: 3 months]
- Pain (Visual-Analog Scale) [Time Frame: 3 months]
 Measure of the subjective symptom of pain.

Walking distance (treadmill) if possible [Time Frame: 3 months]

Estimated Enrollment: 240

Study Start Date: January 2015
Estimated Study Completion Date: December 2018

Estimated Primary Completion Date: December 2017 (Final data collection date for primary

outcome measure)

Arms	Assigned Interventions
Experimental: Adipose-derived stem cell Mesenchymal stem cells derived from adipocyte transplantation	Biological: Adipose-derived stem cell stem cell acquisition, processing and reinfection, to evaluate the efficacy of adipose-derived stem cell.
Placebo Comparator: saline saline injections	Biological: saline

Detailed Description:

Diabetic foot is one of the most serious chronic complications of diabetic patients, and still lacking effective treatments.

Stem cell therapy has been a new and effective therapy in recent years for diabetic foot. Combined with the previous studies of our research group, this study intends to transform part of the results of this research, establish an optimal clinical research program, and attempts to break the technical bottleneck in the stem cell therapy for treating diabetes related vascular complications.

Eligibility

Information from the National Library of Medicine



Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 18 Years to 80 Years (Adult, Senior)

Sexes Eligible for Study: All Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Diabetes mellitus Type 2 or Type 1
- Age between 18-80 years
- Chronic foot ulcer more than 6 weeks
- No sufficient response to best standard care delivered for six weeks.
- PAD up to Fontaine stage III or IV period
- CLI with the ankle brachial index (index ankle-brachial, ABI) <0.7 and (or) the -percutaneous oxygen partial pressure (oxygen tension transcutaneous, TcPO2) <30mmHg

Exclusion Criteria:

- HbA1c >12%
- Hemoglobin <10 mg/dl
- Creatinine clearance rate <30ml/min
- Systemic bacterial, viral infections (Mei Du, hepatitis, cytomegalovirus infection, HIV, B19 infection, herpes virus infection) and sepsis
- Have accepted the treatment of stem cells or growth factors
- Have a history of malignant disease
- Pregnancy
- Mental illness history
- Abnormal coagulation function
- Allergic reaction
- Severe cardiac insufficiency (III-IV NYHA)
- Using vasoactive substances

Contacts and Locations

Information from the National Library of Medicine



To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number):

NCT02831075

Contacts

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Locations

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Principal Investigator: Jie Shen

Sponsors and Collaborators

Jie Shen

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The Fifth Affiliated Hospital of Southern Medical University

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Investigators

Principal Investigator: Jie Shen The Third Affiliated Hospital of Southern Medical University

More Information

Responsible Party: Jie Shen, professor, The Third Affiliated Hospital of Southern Medical

University

ClinicalTrials.gov Identifier: NCT02831075 History of Changes

Other Study ID Numbers: Southern Medical University

First Submitted: July 9, 2016

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Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: Undecided

Keywords provided by Jie Shen, The Third Affiliated Hospital of Southern Medical University:

Adipose-derived Stem Cells

Additional relevant MeSH terms:

Ischemia

Diabetic Foot

Vascular Diseases

Peripheral Vascular Diseases

Peripheral Arterial Disease

Pathologic Processes

Diabetic Angiopathies

Cardiovascular Diseases

Foot Ulcer

Leg Ulcer

Skin Ulcer

Skin Diseases

Diabetes Complications

Diabetes Mellitus

Endocrine System Diseases

Diabetic Neuropathies

Atherosclerosis

Arteriosclerosis

Arterial Occlusive Diseases