

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation the safety of umbilical cord-derived mesenchymal stem cells transplantation in the patients with critical limb ischemia (Phase I clinical trial)

Protocol summary

Study aim

Evaluation the safety of umbilical cord-derived stem cell transplantation in the recovery of patients with threatening limb ischemia

Design

Phase I Clinical Trial, There is no control group and a treatment group with 5 patients, To evaluate safety (Safety) with the minimum therapeutic dose

Settings and conduct

Razi Hospital

Participants/Inclusion and exclusion criteria

critical limb ischemia patients will be included in this study according to the inclusion criteria ((Aged \geq 18 to \leq 60 years, Type I or II DM, No option patients) and exclusion criteria (Advanced CLI, CLI Rutherford Category 4, Subjects with arterial insufficiency, Clinical evidence of invasive infection on index leg, Severe hypertension, platelet count $<$ 50,000/ μ L, Pregnant and lactating women). Patients will be informed of this study by their physician.

Intervention groups

umbilical cord-derived stem cell transplantation in the patients with threatening limb ischemia, There is no control group

Main outcome variables

The area of wound healing; Painless marching condition; CT angiography; Existence of peripheral pulses; transcutaneous oxygen saturation (TCOS); Visual Analog Score of pain; Pain on the Visual Analogue Scale (VAS); Reduced limb amputation; Temperature change on thermography; Angiogenesis - collateral blood vessels by Magnetic resonance angiogram (MRA)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211021052828N2**

Registration date: **2022-05-15, 1401/02/25**

Registration timing: **registered_while_recruiting**

Last update: **2025-12-21, 1404/09/30**

Update count: **1**

Registration date

2022-05-15, 1401/02/25

Registrant information

Name

Elham Vojoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3376 4270

Email address

elhamvojoudi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-14, 1401/02/24

Expected recruitment end date

2022-11-15, 1401/08/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the safety of umbilical cord-derived mesenchymal stem cells transplantation in the patients

with critical limb ischemia (Phase I clinical trial)

Public title

Safety and efficacy of umbilical cord-derived mesenchymal stem cells treatment for patients with Critical Limb Ischemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 18–60 years patients with Type I or II diabetes, established more than one year ago Glycosylated hemoglobin (HbA1c) < 8% Patients suffering from infrapopliteal occlusive disease with rest pain and ischemic ulcer/necrosis, who are not eligible for or have failed traditional revascularization treatment as per the investigators judgment (No option patients) Subjects with poor or no revascularization option (surgical or endovascular) classified as CLI Rutherford Category III-5 or Patients in Rutherford- III-6 as the gangrene extends maximally up to the metatarsal head but limited to toes (Patients with wet gangrene must undergo wound debridement/amputation before screening). For these patients, one of the following options must be confirmed and documented at screening: Ankle systolic pressure < 70 mmHg, systolic toe pressure < 50 mmHg, poor or no revascularization option, since the revascularization using surgical or endovascular methods are not feasible in the investigator opinion due to the anatomy of existing vessels and/or existing comorbidity and/or previously failed surgical or endovascular revascularization.

Exclusion criteria:

Advanced CLI with major tissue loss due to the significant ulceration/gangrene proximal to the metatarsal heads (CLI Rutherford Category 6). Significant ulceration/gangrene means any ulceration that extends beyond the subcutaneous tissue layer, or any gangrene or tissue necrosis proximal to the metatarsal heads CLI Rutherford Category 4 Subjects with arterial insufficiency in the lower limb as a result of acute limb ischemia or an immunological or inflammatory or non-atherosclerotic disorder (e.g., thromboangiitis obliterans (Buerger's Disease), systemic sclerosis (both limited and diffuse forms)) Clinical evidences of invasive infection on the targeted leg with the major tissue loss in the mid-foot or heel involving tendon and/or bone, and/or when intravenous antibiotics are required to treat the infection according to the Investigator At screening, the presence of only neuropathic ulcers on the targeted leg Amputation at the talus or above parts of the targeted leg major amputation within the first month after randomization Severe hypertension according to the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure platelet count < 50,000/μL International normalized ratio (INR) > 1.5 for patients on anticoagulant medication .INR > 1.5 is allowed when the Investigator and the haematologist consider the patient eligibility for BM collection. Evidence of moderate to severe hepatocellular dysfunction according to the physician Subjects who may not be healthy enough to successfully complete all protocol requirements including BM collection, or who are not expected to survive more than 12 months. For

example: a. Concurrent severe congestive heart failure (New York Heart Association Classes III and IV). b. Patients with the left ventricular ejection fraction < 35%. c. Life-threatening ventricular arrhythmias, unstable angina (characterized by increasingly frequent episodes with modest exertion or at rest, worsening severity, and prolonged duration), and/or myocardial infarction within four weeks before screening. d. Coronary artery bypass grafting or percutaneous coronary intervention within one month before screening. e. A renal and/or carotid revascularization procedure within one month of screening. f. Transient ischemic attack within three months prior to screening. g. Deep vein thrombosis within three months prior to screening. h. Subjects with immunocompromised conditions, organ transplant recipients and/or subjects in need of immunosuppressive therapy. i. neurodegenerative disease such as Alzheimer disease Subjects who participate in another clinical interventional trial Patients who are contraindicated for MRA Patients with deep vein thrombosis in any limb Documented terminal illness or cancer or any concomitant disease process with a life expectancy of <1 year History of severe alcohol or drug abuse within 3 months of screening Hb < 10 gm% for males, Hb% < 9 gm% for females, serum creatinine ≥ 2mg%, Total serum Bilirubin ≥2mg% Pregnant and lactating women

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1

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

Ethics committee of Guilan university of medical sciences

Street address

Sardare Jangal Blvd

City

Rasht

Province

Guilan

Postal code

4144895655

Approval date

2022-04-05, 1401/01/16

Ethics committee reference number

IR.GUMS.REC.1401.015

Health conditions studied**1****Description of health condition studied**

Critical Limb Ischemia

ICD-10 code

G173.9

ICD-10 code description

Critical Limb Ischemia

Primary outcomes**1****Description**

Wound healing extent

Timepoint

Before intervention and 1, 2, 3 months after implantation of stem cells

Method of measurement

Square centimeters

2**Description**

Temperature changes

Timepoint

Before intervention and 1, 2, 3 months after implantation of stem cells

Method of measurement

Thermography

3**Description**

Peripheral pulses

Timepoint

Before intervention and 1, 2, 3 months after implantation of stem cells

Method of measurement

Palpation

4**Description**

Pain on the Visual Analogue Scale (VAS)

Timepoint

Before intervention and 1, 2, 3 months after implantation of stem cells

Method of measurement

Examination

Secondary outcomes**1****Description**

Ankle-brachial index

Timepoint

Before intervention and 1, 2, 3 months after implantation of stem cells

Method of measurement

The ABI is performed by measuring the systolic blood pressure from both brachial arteries and from both the dorsalis pedis and posterior tibial arteries after the patient has been at rest in the supine position for 10 minutes.

2**Description**

Reduced limb amputation

Timepoint

1, 2, 3 months after implantation of stem cells

Method of measurement

Observation

3**Description**

collateral blood vessels angiogenesis

Timepoint

One, 2, 3 months after implantation of stem cells

Method of measurement

Magnetic resonance angiogram (MRA)

4**Description**

CT Angiography

Timepoint

Before intervention and 1, 2, 3 months after implantation of stem cells

Method of measurement

X-Ray

Intervention groups**1****Description**

Intervention group: This study is defined in phase I of the clinical trial, so there is no control group and a treatment group with 5 patients will be examined for safety (Safty) with a minimum dose of therapy.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi University Hospital

Full name of responsible person

Elham Vojoudi

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Sardare Jangal Blvd, Razi University Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

Street address

The old building of the Faculty of Health, in front of 17 Shahrivar Hospital, Namjoo St., Shahid Siadati St., Rasht, Guilan, Iran

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naghi@gums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

20

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

2

Sponsor

Name of organization / entity

Sinacell Research and Production Co.

Full name of responsible person

SeyedVahid Ahmadi

Street address

No. 162, Noavari Ave., Pardis Technology Park, 20th km of Damavand Rd., Tehran

City

Tehran

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Tehran

Postal code

1654120596

Phone

+98 21 7625 0661

Email

info@sinacellco.com

Web page address

<https://www.sinacellco.com/?lang=en>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sinacell Research and Production Co.

Proportion provided by this source

80

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Elham Vojoudi

Position

Assistant Professor of Tissue Engineering, Guilan University of medical sciences

Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Tissue Engineering

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Elham Vojoudi

Position

Assistant Professor of Guilan University of Medical
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Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some portion of the data, such as information about the
main outcome can be shared.

When the data will become available and for how long

Two years

To whom data/document is available

physician and the treatment staff

Under which criteria data/document could be used

Physicians to investigate and improve the treatment

From where data/document is obtainable

Elham vojoudi

What processes are involved for a request to access data/document

By email and necessary tasks and administrative
procedures

Comments