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 (Safty) 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 critria ((Aged ≥ 18 to ≤ 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/µL, 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 erea 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
elhamvojoodi@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 norevascularization 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 eligiblity 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
Street address
Sardare Jangal Blvd,Razi University Hospital
City
Rasht
Province
Guilan
Postal code
4144895655
Phone
+98 13 3354 2460
Email
elhamvojoodi@yahoo.com

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
City
Rasht
Province
Guilan
Postal code
4144895655
Phone
+98 13 3333 6394
Email
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
Province
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
Street address
Razi University Hospital, Sardare Jangal Blvd, Rasht, Guilan, Iran
City
Rasht
Province
Guilan
Postal code

4144895655

Phone
+98 13 3354 2460

Fax

Email
elhamvojoodi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Elham Vojoudi

Position
Assistant Professor of Tissue Engineering Langroud School of Allied Medical Sciences Guilan Universi

Latest degree
Ph.D.

Other areas of specialty/work
Tissue Engineering

Street address
Razi University Hospital, Sardare Jangal Blvd, Rasht, Guilan, Iran

City
Rasht

Province
Guilan

Postal code
4144895655

Phone
+98 13 3354 2460

Email
elhamvojoodi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Elham Vojoudi

Position
Assistant Professor of Guilan University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Tissue Engineering

Street address
Razi University Hospital, Sardare Jangal Blvd, Rasht, Guilan, Iran

City
Rasht

Province
Guilan

Postal code
41448955655

Phone
+98 13 3354 2460

Email
elhamvojoodi@yahoo.com

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