Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Evaluation of safety and efficacy of stromal vascular fraction on foot diabetic wound-clinical trial phase I and II

Protocol summary

Study aim

Evaluation of safety and efficacy of stromal vascular fraction on foot diabetic wound, clinical trial, phase I and II

Design

This clinical trial is designed for phases I and II with Randomization using block method with two control and intervention groups and is single-blind. The sample size is 62. The allocation rate is 1:1, and the type of study is parallel.

Settings and conduct

This study will be performed at the Burns and Regenerative Medicine Research Center at Velayat hospital. In the intervention group, a stromal vascular fraction (SVF) will be injected using mesogan device in the desired areas with a depth of 1 to 2 mm in a width of 1% equal to 10 to 17 cm at intervals of 1 in 1 cm with a volume of 0.1 cc.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having chronic diabetic foot ulcer; age range between 30 to 60 years; having a single wound on the foot and limb extremities that has not been healed for at least four weeks; body mass index between 18 to 25; ABI / TBI ratio greater than 0.9. Exclusion criteria: smoking; alcohol consumption; drug addiction; taking drugs that may interfere with wound healing.

Intervention groups

In the intervention group, SVF will be injected using mesogan device in the desired areas with a depth of 1 to 2 mm in a width of 1% equal to 10 to 17 cm at intervals of 1 in 1 cm with a volume of 0.1 cc. Control group: The control group does not receive any placebo, only routine interventions.

Main outcome variables

Evaluation of safety of SVF (mortality, fever, infection, systemic adverse effects such as blood pressure and heart rate). Secondary outcomes (wound closure, wound healing; amputation, pain, itching, burning, inflammation, discharge).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210212050334N2**
Registration date: **2021-10-20, 1400/07/28**
Registration timing: **prospective**

Last update: **2021-10-20, 1400/07/28**
Update count: **0**

Registration date

2021-10-20, 1400/07/28

Registrant information

Name

Amaneh Mohammadi Roushandeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3333 1520

Email address

mohammadi_roushandeh@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and efficacy of stromal vascular fraction on foot diabetic wound-clinical trial phase I and II

Public title
Evaluation of safety and efficacy of stromal vascular fraction on foot diabetic wound-clinical trial phase I and II

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having chronic outpatient diabetic foot ulcer Age range from 30 to 60 years Having a single wound on the foot and limb terminals (fingers, sole, heel, toes) within four works without repair Body Mass index 18-25 ABI / TBI ratio greater than 0.9.

Exclusion criteria:
Smoking, Alcohol consumption Drug addiction Taking drugs that may interfere with wound healing, such as corticosteroids, immunosuppressive agents, and cytotoxic agents. A concomitant disease that may interfere with wound healing, such as cancer, vasculitis, kidney, liver, or heart failure. Osteomyelitis

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Investigator

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
In the present study, the block randomization method will be used. In this study, by equalizing the size of the blocks, blocks of size 6 (three participants in the intervention group and three participants in the control group) will be used. Related software, R software package, will be used. We use the opaque sealed envelopes method for concealment. Random sequences will be written on the cards. Then the cards will be placed inside the envelope. In order to maintain the created random sequence, numbers will be written on the outer surface of the envelopes. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the project, one of the envelopes will be opened in order and the assigned group of that participant is revealed according to the order of entry of eligible participants.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this research, the single-blind method will be used. Due to the removal of fat by the physician from the patient, blinding of physician and evaluators will not be possible. Only the person who will assign the groups (investigator) will be blind.

Placebo
Not used

Assignment
Parallel

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
3th floor, Burn and Regenerative Medicine ResearchCenter, Velayat Hospital, Namjo street, Rasht, Guilan

City
Rasht

Province
Guilan

Postal code
4193713194

Approval date
2021-09-14, 1400/06/23

Ethics committee reference number
IR.GUMS.REC.1400.282

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcers

ICD-10 code
E11.621

ICD-10 code description
Type 2 diabetes mellitus with foot ulcer

Primary outcomes

1

Description
Mortality rate

Timepoint
24 hours and one week after SVF injection

Method of measurement
Patient record

2

Description
Adverse systemic complications

Timepoint
24 hours and one week after SVF injection

Method of measurement
Barometer and diagnostic tests

3

Description
Fever
Timepoint
24 hours and one week after SVF injection
Method of measurement
Thermometer

4

Description
Infection
Timepoint
24 hours and one week after SVF injection
Method of measurement
Examination of the wound by the treating physician

Secondary outcomes

1

Description
Wound healing
Timepoint
1,7, 28 and 60 days after SVF injection
Method of measurement
Examination, wound diameter decreases

2

Description
wound edema
Timepoint
1,7, 28 and 60 days after SVF injection
Method of measurement
Medical examinations and checklist

3

Description
Neuropathy
Timepoint
1,7, 28 and 60 days after SVF injection
Method of measurement
Physician diagnosis and check list

Intervention groups

1

Description
Intervention group: The prepared SVF will be injected in the desired areas with a depth of 1 to 2 mm in a width of 1%, equal to 10 by 17 cm at intervals of 1 in 1 cm with a volume of 0.1 cc, using the mesogan device.
Category
Treatment - Other

2

Description
Control group: The control group will not receive the placebo and no intervention will be performed for them. This group will receive all routine treatments.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat hospital
Full name of responsible person
Amaneh Mohammadi Roushandeh
Street address
3 floor, Burn and Regenerative Medicine Research Center, Velayat hospital, Namjo street, Rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Fax
+98 13 3336 8540
Email
mohammadi_roushandeh@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammad Reza Naghipour
Street address
Deputy of Research and Technology, Shahid Siadati Street, Namjoo Street, Rasht, Guilan
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Fax
+98 13 3336 8540
Email
mohammadi_roushandeh@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

100

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

Person responsible for general inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Amaneh mohammadi roushandeh

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Regenerative medicine

Street address
3th floor, Burn and Regenerative Medicine Research Center, Velayat Hospital, Namjo street, Rasht, Guilan

City
Rasht

Province
Guilan

Postal code
4193713194

Phone
+98 13 3336 8540

Fax
+98 13 3336 8540

Email
mohammadi_roushandeh@gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Amaneh Mohammadi Roushandeh

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Regenerative Medicine

Street address
3th floor, Burn and Regenerative Medicine Research Center, Velayat Hospital, Namjo street, Rasht, Guilan

City
Rasht

Province
Guilan

Postal code
4193713194

Phone
+98 13 3336 8540

Fax
+98 13 3336 8540

Email
mohammadi_roushandeh@gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Amaneh Mohammadi Roshandeh

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Regenerative Medicine

Street address
3th floor, Burn and Regenerative Research Medicine Center, Velayat Hospital, Namjo street, Rasht, Guilan

City
Rasht

Province
Guilan

Postal code
4193713194

Phone
+98 13 3336 8540

Fax
+98 13 3336 8540

Email
mohammadi_roushandeh@gums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Age,sex, side effect

When the data will become available and for how long
After publishing the results in the article

To whom data/document is available
Universities

Under which criteria data/document could be used

only for study

From where data/document is obtainable

Dr.Amaneh Mohammadi Roushandeh Email: mohammadi_roushandeh@gums.ac.ir

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

The request must be written to the Vice Chancellor for Research of Guilan University of Medical Sciences. The request is sent to the principal investigator and the researcher will send the documents to the deputy. The applicant can receive the documents from the deputy.

Comments