

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The Effect of 12-week Aerobic and Lower Extremity Resistance Exercises on Healing of Foot Ulcers in Type 2 Diabetic Patients

Protocol summary

Study aim

To assess and compare the effects of a supervised structured exercise program on Wound Surface Area, Wound Depth, Ankle-Brachial Index, Blood Parameters (IL-6, IL-10, IGF-1, VEGF, TNF- α) and Quality of Life among type II diabetic patients with foot ulcers and the control group

Design

Two arm parallel group randomized controlled trial with blinded outcome assessment on 26 patients. Randomization using 6x4 concealed blocks and Online Randomization software

Settings and conduct

Outcome assessor will be blinded to allocation both before and after the intervention. The study will be carried out in Tehran University of Medical Sciences Diabetes Center No.1

Participants/Inclusion and exclusion criteria

Type 2 diabetic patients with foot ulcer and without any extreme or life threatening complications such as immunodeficiency, heart failure or any other organ disease. Average diabetic foot patients who can benefit from supervised structured exercise.

Intervention groups

The interventional group receives standard care (daily wound dressing change) + 12 weeks (3 sessions/week) of supervised structured exercise (aerobic + resistance) and structured home based exercise in the other 3 days of the week.

Main outcome variables

Wound surface area

General information

Reason for update

The temporary shutdown of university treatment centers and the lack of access to the patients due to COVID-19 pandemic, forced the research team to postpone the initiation of sampling and research process so far. In the

meantime, some new research results and articles were obtained by the research team that based on which, the sample size and design of the current research needs some editing. It is important to mention that the sampling process has not begun yet.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201214049723N1**

Registration date: **2021-01-07, 1399/10/18**

Registration timing: **prospective**

Last update: **2021-06-09, 1400/03/19**

Update count: **1**

Registration date

2021-01-07, 1399/10/18

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of 12-week Aerobic and Lower Extremity Resistance Exercises on Healing of Foot Ulcers in Type 2 Diabetic Patients

Public title

The Effect of 12-week Aerobic and Lower Extremity Resistance Exercises on Healing of Foot Ulcers in Type 2 Diabetic Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Type II DM according to ADA criteria for less than 20 years Receiving medical care (diet, oral agents, insulin) throughout the disease course Stable hypoglycemic medications (type & dosage) within the last 2 months Existence of at least one foot ulcer with Wound Surface Area $\leq 16 \text{ cm}^2$ The ulcer must be classified as grade 2, stage A or C under the UTCS Stable anti inflammatory drugs (drugs prescribed to control HTN or hyperlipidemia) during the last 3 months At least 18 years of age BMI < 35 $0.7 \leq \text{ABI} \leq 1.4$ $6.5\% \leq \text{HbA1C} \leq 9.5\%$ $100 \leq \text{FBS} \leq 250 \text{ mg/dl}$ Sedentary lifestyle for the last 6 months

Exclusion criteria:

Cognitive or mental deficit Wound treatments other than standard care (deemed to be required by the physician) such as growth factors, NPWT, hyperbaric oxygen, special dressings, etc. Ulcer requiring surgical operations other than debridement Non-diabetic ulcers such as electrical, chemical or radiation burns, etc. Pregnancy or breast feeding Infection or OM Critical limb ischemia or lower extremity gangrene Proliferative retinopathy or history of retinal detachment Moderate or severe kidney disease History of major lower extremity amputation Severe liver disease Uncontrolled HTN or BP higher than 160/95 mmHg Life-threatening disease such as malignancy History of DVT during the last 6 months Active cellulitis or collagen vascular disease Active Charcot Present history of smoking or alcoholism Dialysis Immunodeficiency caused by immunosuppressant usage or chemotherapy during the past 2 months, radiotherapy within the last 4 months or systemic diseases Presence of any overt cardiovascular condition diagnosed by cardiologist that prevents the patient from performing vigorous activities Any kind of disease or condition (orthopedic, neurologic, pulmonary, arthritis, etc.) that limits or contraindicates physical activity Presence of any condition considered as absolute contraindication for physical activity by the ACSM's guideline Participating in any experimental or non-experimental program that requires regular physical activity

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

- Data analyser

Sample size

Target sample size: 26

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified block randomization using "dressing type" as matching factor between the groups. Online Randomization software will be used in randomization process. There will be 6 blocks, each containing 4 letters (e.g. AABB) as half of each block belongs to the control group and the other half belongs to the interventional group. These 6 blocks will be sorted out in a randomized fashion as well. The blocks will be placed in different sealed envelopes prepared by a third party that has no participation in any of the research stages whatsoever. Each time one of these envelopes will be unsealed randomly and 4 patients will be allocated according to the sequence of the letters inside that block. Then the envelope will be sealed and put in its position again.

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome assessor will be blind to allocation before and after the intervention period.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

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Iran University of Medical Sciences, Hemmat Hwy.

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Approval date

2020-12-06, 1399/09/16

Ethics committee reference number

IR.IUMS.REC.1399.969

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

Type 2 diabetic foot ulcer

ICD-10 code

E11.621

ICD-10 code description

Type 2 diabetes mellitus with foot ulcer

Primary outcomes

1

Description

Wound surface area

Timepoint

Baseline, at the end of 4th, 8th and 12th weeks

Method of measurement

Taking pictures and using the "NIH Imagej" software for wound surface area measurement

Secondary outcomes

1

Description

Quality of life

Timepoint

Baseline and the end of 12th week

Method of measurement

Iranian version of The Short Form 36 Health Survey (SF-36)

2

Description

Ankle Brachial Index (ABI)

Timepoint

Baseline, at the end of 4th, 8th and 12th weeks

Method of measurement

Ankle Brachial Index measurement device which measures systolic blood pressure at arm and ankle levels and calculates the exact value

3

Description

5 blood parameters (Interleukin-6, Interleukin-10, Insulin-like Growth Factor-1, Tumor Necrosis Factor- α and Vascular Endothelial Growth Factor)

Timepoint

Baseline and at the end of 12th week

Method of measurement

Taking blood samples and using special laboratory kits

4

Description

Wound depth

Timepoint

Baseline, at the end of 4th, 8th and 12th weeks

Method of measurement

Using wound depth measurement sterile probe and disposable paper ruler

Intervention groups

1

Description

Control group: Wound washing using saline and wound dressing change as standard care

Category

Treatment - Other

2

Description

Intervention group: Wound washing using saline and wound dressing change as standard care + 12 weeks (3 sessions/week) of supervised aerobic and resistance exercise and home based range of motion exercise (3 days/week)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

TUMS Diabetes Center No.1

Full name of responsible person

Dr. Ensieh Nasli Esfahani

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

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Position

Student

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Iran University of Medical Sciences will decide whether to publish the data or not.

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available

Data Dictionary

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