Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Low level laser with Ga-As (904 nm) on expression of angiogenic factors (VEGF, NO, VEGFR-2, HIF-1α), Oxygen saturation of peripheral blood and wound surface area in ischemic diabetic foot ulcers

Protocol summary

Summary

Defects in vessels and neovascularization makes diabetic chronic wounds difficult to treat. Reduce the production of angiogenic factors is involved an important inhibit in the construction of new vessels in diabetic foot ulcers. Low level laser therapy as a therapeutic treatment modality can effect on angiogenesis and release of its factor in wound site. The purpose of this study is to examine the changes of blood serum factors including VEGF, VEGFReceptor-2, NO and HIF-1α, measurements of Oxygen saturation of peripheral blood in around wound and wound surface area in ischemic diabetic foot ulcers after LLLT, Therefore, 30 patients with ischemic diabetic foot ulcer were randomly and single blind(patients) divided into two groups: Ga-As laser (No=15) and placebo (No=12). In laser group, Ga-As laser (2 j/cm2) with conventional therapy and in placebo group, conventional therapy with laser therapy While it is turned off were applied, for 12 sessions, every other day . On the first and last treatment session, before and after intervention, Blood sample are taken from all patients in the both groups for VEGF, VEGFreceptor-2, NO and HIF-1α measurement. Oxygen saturation of peripheral blood and wound surface area are measured at first, sixth and twelfth treatment sessions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051717723N1**
Registration date: **2015-05-08, 1394/02/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-05-08, 1394/02/18

Registrant information

Name

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Name of organization / entity

Tarbiat Modares University

Country

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Recruitment status

Recruitment complete

Funding source

Tarbia Modares University, Tehran

Expected recruitment start date

2015-04-05, 1394/01/16

Expected recruitment end date

2015-11-06, 1394/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Low level laser with Ga-As (904 nm) on expression of angiogenic factors (VEGF, NO, VEGFR-2, HIF-1α), Oxygen saturation of peripheral blood and wound surface area in ischemic diabetic foot ulcers

Public title

Low level laser effect on improving the blood flow in diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: 1. Diabetic patients with ischemic diabetic foot ulcers (of both sexes) aged 40 to 60 years 2. 32> BMI> 25 3.Wagner grade 2 diabetic ulcers and ulcer size larger than the standard 2 cm below the ankle area 4. Mild to moderate neuropathic diabetic foot screening table (UK) 5. 0.50 ˂ Ankle Brachial Index < 0.9 6. HbA1c < 8 7. Non-smoking 8. No signs of wound infection 10. No Having kidney disease(serum creatinine level less than 2 mg / dL) 11. No Having body fracture occurred recently. 12. No Having skin diseases

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tarbiat Modares University

Street address

Physiotherapy Department, Tarbiat Modares University, Jalal Ale Ahmad Highway

City

Tehran

Postal code

Approval date

2013-07-06, 1392/04/15

Ethics committee reference number

D 52.2567

Health conditions studied

1

Description of health condition studied

Diabet Melitus Type 2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Ankle Brachial Index

Timepoint

session 1 and 12

Method of measurement

Digital Manometer

2

Description

oxygen saturation of peripheral blood

Timepoint

session 1 , 6,12

Method of measurement

Pulse oxymeter

3

Description

Wouns surface area

Timepoint

session 1 , 6,12

Method of measurement

Imaging

4

Description

Nitric Oxide

Timepoint

session 1 and 12

Method of measurement

biochemical analysis

5

Description

HIF-1α

Timepoint

session 1 and 12

Method of measurement

biochemical analysis

6

Description

Vascular Endothelial Growth Factor

Timepoint

session 1 and 12

Method of measurement

biochemical analysis

7

Description
Vascular Endothelial Growth Factor-Receptor 2
Timepoint
session 1 and 12
Method of measurement
biochemical analysis

Secondary outcomes

1

Description
Assessment of physical activity and pain
Timepoint
Start and end of study
Method of measurement
standard Questionnaire SF-36

Intervention groups

1

Description
In Placebo group, Patients will be treated with standard therapy and laser,While it is turned off ,every other day, for 12 sessions.
Category
Treatment - Devices

2

Description
In Laser therapy group,patients will be treated with Ga-As laser, 2 j/cm2, 90 mW and standard therapy, every other day, for 12 sessions.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomeini Hospital
Full name of responsible person
Dr Manoochehr Iranparvar Alamdari
Street address
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tarbiat Modares University
Full name of responsible person
Dr Gity Torkaman
Street address
Physiotherapy Department, Tarbiat Modares University, Jalal Ale Ahmad Highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tarbiat Modares University
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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PhD candidate for physical therapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty