

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effect of Low level laser with Ga-As (904 nm) on expression of angiogenic factors (VEGF, NO, VEGFR-2, HIF-1 α), 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, VEGFR-2, NO and HIF-1 α , 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, VEGFR-2, NO and HIF-1 α 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-1 α), 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. $32 > \text{BMI} > 25$ 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. $0.50 \leq \text{Ankle Brachial Index} < 0.9$ 6. $\text{HbA1c} < 8$ 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-1 α

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

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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

Tabiat Modarres Univercity

Full name of responsible person

Dr Gity Torkaman

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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