

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison between cryotherapy along laser therapy effects and specific laser therapy effects alone on diabetic foot ulcers, a randomized clinical trial

Protocol summary

Study aim

for Comparison of cryotherapy along laser therapy effects and specific laser therapy effects alone on diabetic foot ulcers

Design

In this study, 30 patients with diabetic foot ulcers, grade 2 and 3 will be randomly divided into three groups by randomization blocks (10 patients in each group).

Settings and conduct

The study will be conducted in the diabetes clinic and physiotherapy department of the Semnan Kowsar Hospital (Iran).

Participants/Inclusion and exclusion criteria

Participating are diabetic patients with diabetic foot ulcers. Inclusion criteria: Past history of diabetes more than 5 years, age more than 50 years, having at least one noninfectious, non-ischemic and non-hemorrhagic diabetic foot ulcer. Exclusion criteria: Creatinine level higher than 2, ischemia, infection (fever, leukocytosis, elevated ESR level), receiving of corticosteroid or immunosuppressive drug, ulceration due to any causes other than diabetes mellitus, large vessels involvement, chemotherapy, underlying disease, sensitivity to cryotherapy .

Intervention groups

Group A (Cryotherapy and Laser Therapy): Patients in this group, receive cold therapy with ice pack for 30 minutes per session, and laser therapy (low power with an intensity of 3 J/cm², 6 sessions per week for 4 weeks in addition to routine. Second group (laser therapy): Patients in this group, receive laser therapy (low power with an intensity of 3 J/cm², 6 sessions per week for 4 weeks in addition to routine treatments. Third Group (control): Patients in this group will receive only routine therapies.

Main outcome variables

Reduction in diabetic foot ulcer size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151020024625N7**

Registration date: **2018-04-23, 1397/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-23, 1397/02/03**

Update count: **0**

Registration date

2018-04-23, 1397/02/03

Registrant information

Name

Mehrdad Zahmatkesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3343 7844

Email address

mehrdadzahmatkesh@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between cryotherapy along laser therapy effects and specific laser therapy effects alone on diabetic foot ulcers, a randomized clinical trial

Public title

Efficacy of cryotherapy along laser therapy and laser therapy alone on diabetic foot ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Past history of diabetes more than 5 years age more than 50 years having at least one noninfectious, non-ischemic and non-hemorrhagic diabetic foot ulcer.

Exclusion criteria:

Creatinine level higher than 2 Ischemia Infection (fever, leukocytosis, elevated ESR level) Receiving of corticosteroid or immunosuppressive drug, Ulceration due to any causes other than diabetes mellitus Large vessels involvement Chemotherapy Underlying disease Sensitivity to cryotherapy

Age

From 50 years old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into three groups by randomization blocks

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee, Semnan University of Medical Sciences

Street address

Basidj Boulevard

City

Semnan

Province

Semnan

Postal code

3519899951

Approval date

2018-02-06, 1396/11/17

Ethics committee reference number

IR.SEMUMS.REC.1396.232

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

E13.51

ICD-10 code description

Other specified diabetes mellitus with diabetic peripheral angiopathy without gangrene

Primary outcomes

1

Description

Reduction in diabetic foot ulcer size

Timepoint

30 days after intervention

Method of measurement

Physical Examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A: Patients in this group, receive cold therapy with ice pack for 30 minutes per session, and laser therapy (low power with an intensity of 3 J/cm², 6 sessions per week for 4 weeks in addition to routine.

Category

Treatment - Devices

2

Description

Second intervention group (laser therapy): Patients in this group, receive laser therapy (low power with an intensity of 3 J/cm², 6 sessions per week for 4 weeks in addition to routine treatments.

Category

Treatment - Devices

3

Description

Control group: Patients in this group will receive only

routine therapies.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Majid Forootan

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Email

dr_forotan@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohammad Reza Asgari

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Majid Forootan

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Majid Forootan

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mehrdad Zahmatkesh

Position

Research Expert

Latest degree

Bachelor

Other areas of specialty/work

Biostatistics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not 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

Results of statistical Analysis

When the data will become available and for how long

After completing the project

To whom data/document is available

Only the study researchers and Referee

Under which criteria data/document could be used

For similar studies

From where data/document is obtainable

Dr. Majid Forootan

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

Calling and Email

Comments