

# 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/cm<sup>2</sup>, 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/cm<sup>2</sup>, 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/cm<sup>2</sup>, 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/cm<sup>2</sup>, 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

**Street address**

Basidj Boulevard

**City**

Semnan

**Province**

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**Postal code**

3519899951

**Phone**

+98 23 3142 2120

**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

**Street address**

Basidj Boulevard

**City**

Semnan

**Province**

Semnan

**Postal code**

3519899951

**Phone**

+98 23 3344 1022

**Email**

sem.ums.res@gmail.com

**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**

**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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**Email**

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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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**Email**

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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**