To study the effect of infrared radiation on the healing of lower extremity ulcers in diabetic foot

Protocol summary

Summary
Background: Diabetic foot ulcer is a worldwide health care concern affecting tens of thousands of patients. If this ulcer is not treated well, it can create irretrievable difficulties. This study was designed to study the effect of infrared radiation on the healing of diabetic foot ulcer.

Method: This was a clinical trial that was performed among hospitalized patients in Dr. Ganjavian hospital of Dezful. Sampling was purposeful and 50 patients, with stage 1 or 2 Diabetic foot ulcer, were selected. Then they were divided randomly in two groups. 25 patients were treated by routine dressing and 25 patients by Infared radiation besides the routine dressing. All subjects matched using age, sex, Body Mass Index (BMI), stage of Diabetic foot ulcer, location of ulcer. Ulcers in two groups, was assessed by checklist in the zero, first, second, third and fourth weeks. Assessment parameters contain: degree of sore, color, periphery tissue of sore and amount of ulcers exudate. State of ulcers was determined and categorized to complete healing, partial healing, without improvement or worsening.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138903034011N1
Registration date: 2012-05-17, 1391/02/28
Registration timing: retrospective

Name of organization / entity
Dezful faculty of medical sciences

Country
Iran (Islamic Republic of)

Phone
+98 64 1526 6172

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sadeghi_ali2008@ajmus.ac.ir

Recruitment status
Recruitment complete

Funding source
Private

Expected recruitment start date
2009-11-06, 1388/08/15

Expected recruitment end date
2010-04-04, 1389/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
To study the effect of infrared radiation on the healing of lower extremity ulcers in diabetic foot

Public title
Effect of infrared radiation on the healing of lower extremity ulcers in diabetic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1- diabetic foot ulcer in extremity organs; 2- diabetic foot ulcer of 1 or 2 degree; 3- having diabetes for at least 5 years. Exclusion criteria: 1- addiction; 2-smoking.

Age
From 30 years old to 80 years old

Gender
Both

**Phase**
N/A

**Groups that have been masked**
No information

**Sample size**
Target sample size: 50

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**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
Ahwaz university of medical sciences
Street address
Central organization of Ahwaz university of medical sciences, university town
City
Ahwaz
Postal code
15794 - 61357

**Approval date**
empty

**Ethics committee reference number**
190/20/8/

**Health conditions studied**

1

**Description of health condition studied**
Diabetic foot

**ICD-10 code**
I79.2

**ICD-10 code description**
Peripheral angiopathy in diseases classified elsewhere

**Primary outcomes**

1

**Description**
healing of diabetic foot ulcer

**Timepoint**
Every week

**Method of measurement**
Check list to assess diabetic foot healing

**Secondary outcomes**

1

**Description**
healing time

**Timepoint**
during the study

**Method of measurement**
time from the beginning of study

**Intervention groups**

1

**Description**
Infrared radiation to diabetic foot in case group: use of 250-W tungsten lamp, made by OSRAM Company in Germany, after washing up the ulcer in the routine procedure. Before repeating the dressing, the patient was treated by infra-red radiation, once a day and seven days a week. This was carried out in the following way: a thermometer was placed on the surrounding of the healthy skin to record the temperature of that point and to ensure that the temperature did not exceed 42 degrees centigrade. The distance between the infra-red source and the skin was 30 cm and the radiation time was 20 minutes. The radiation angle was chosen as vertical according to Cosinus Lamiriat law in order to absorb the maximum radiation and then wet dressing was performed.

**Category**
Other

2

**Description**
Routine dressing for control group: patient’s ulcer and its peripheral tissues were immersed in a sterile tub of saline for 20 minutes and then they were dried by sterile gauze and were dressed in a sterile way after being put in a layer of wet gauze. This process was carried out twice a day, seven days a week. In case the dressing was removed because of excessive discharge or wetness, the dressing was repeated.

**Category**
Other

**Recruitment centers**

1

**Recruitment center**
Name of recruitment center
Dr. Ganjavian hospital
Full name of responsible person
Street address
City
Dezful
Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Privait
Full name of responsible person
Ali sadeghi moghaddam
Street address
Dezful faculty of medical Sciences, Dezful
City
Dezful
Grant name
Privait
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Privait
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
empty
Type of organization providing the funding
empty

2
Sponsor
Name of organization / entity
Ahwaz Jundishapur University of Medical Sciences
Full name of responsible person
Ashrafalsadat Hakim
Street address
Faculty of Nursing and Midwifery, Ahwaz Jundishapur University of Medical Sciences
City
Ahwaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahwaz Jundishapur University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
empty
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Dezful faculty of medical sciences
Full name of responsible person
Ali Sadeghi Moghaddam
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Master science of nursing, Faculty member
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Person responsible for updating data

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Email
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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