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 Inferared 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

Last update:
Update count: 0
Registration date
2012-05-17, 1391/02/28

Registrant information
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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/پ

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 Lamirt 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
IDezful faculty of medical Sciences,Dezful
City
Dezful
Grant name

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

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

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

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Dezful faculty of medical sciences
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Master science of nursing, Faculty member
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City
Postal code
Phone
Fax
Email
Web page address
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