Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of hydrocolloid dressing and silver Nano particles in the healing of pressure ulcers in patients with spinal cord injuries

Protocol summary

Summary

This study compares the effect of hydrocolloid dressing and silver nanoparticles on the healing of pressure ulcers in patients with spinal cord injuries with pressure ulcers grade 2 and 3 who were admitted in university hospitals in Tehran. Inclusion criteria are: patients with pressure ulcers grade 2 and 3, age 18 to 65 years, lack of infection in the wound, lack of necrotic tissue, patients who are willing to be changing position every hour and no use of other dressings. Exclusion criteria are: occurrence of malnutrition in the study; surgical Wound; lack of patient cooperation; changing position every hour for more than 10 times during the study and discharge from the hospital before the change in the stage of wound. Characteristics of lesions in 120 patients with BWAT tool will be evaluated. The dressing will be administered by the manufacturer guideline and wound healing evaluation is performed by a process in which the partner does not know the type of dressing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112038286N1**
Registration date: **2011-12-11, 1390/09/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-12-11, 1390/09/20

Registrant information

Name

Fatemeh Bahramnezhad

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hydrocolloid dressing and silver Nano particles in the healing of pressure ulcers in patients with spinal cord injuries

Public title

Pressure ulcer & dressing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with pressure ulcers grade 2 and 3; age 18 to 65 years; lack of infection in the wound or necrotic tissue; patients who are willing to be changing position every hour and no use of other dressings. Exclusion criteria: occurrence of malnutrition in the study; surgical Wound; lack of patient cooperation; changing position every hour for more than 10 times during the study and discharge from the hospital before the change in the stage of wound

Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
6th floor, Centeral building of Tehran University of Medical Sciences, Ghods St, Keshavarz BLD.
City
Tehran
Postal code
Approval date
2011-11-01, 1390/08/10
Ethics committee reference number
90/130/1561

Health conditions studied

1

Description of health condition studied
Pressure Ulcer
ICD-10 code
L89.9
ICD-10 code description
Decubitus ulcer and pressure area, unspecified

Primary outcomes

1

Description
Duration of recovery
Timepoint
After each dressing change
Method of measurement
jJensen wound assessment tool or pressure sore status tool

2

Description
The depth of the wound
Timepoint
After each dressing change
Method of measurement
Jensen wound assessment tool or pressure sore status tool

3

Description
Money spent for dressing change
Timepoint
After each dressing change
Method of measurement
They calculated the total number of dressings and Price

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group (Silver nano-particles) were dressed according to the manufacturer's (How to change, time and frequency of dressing changes) instructions they receive, and depth of wound, duration of wound healing with BWTA will be evaluated
Category
Treatment - Drugs

2

Description
In the control group (Hydrocolloid) were dressed according to the manufacturers (How to change, time and frequency of dressing changes) instructions they receive, and depth of wound, duration of wound healing with BWTA will be evaluated
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Street address
City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Roghayeh Karimi
Street address
6th floor,Centeral building of Tehran University of Medical Sciences, Ghods St, Keshavarz BLD.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
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
Tehran University of Medical Sciences
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Fatemeh Bahramnezhad
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

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City
Tehran
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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