Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effectiveness of Henna (Lawsonia Inermis) on prevention of pressure ulcer

Protocol summary

Summary

This research with the goal of study on effectiveness of Henna (Lawsonia inermis) on prevention of pressure ulcer on hospitalized patients in Intensive Care Units will be done. Inclusion Criteria: No having pressure ulcer on recruitment; to be hospitalized in ICU; no diabetes; Exclusion Criteria: No desire to continue the study; death First 80 hospitalized patients in ICU based on convenience sampling method will be selected, then all of them with closed envelopes method randomly will be allocated into two trial and control groups. Interventions are as follows: In Trial group, beside of massage of sacrum, at one time Henna is placed 15 cm on sacrum and after 30 minutes it will be washed. Then sacrum will be assessed for pressure ulcer signs (e.g. local temperature) at 10 o'clock every day up to one week. In control group only routine nursing care (massage with no material) will be done. Then sacrum will be assessed for pressure ulcer signs (e.g. local temperature) at 10 o'clock every day up to one week. In this study the primary outcome will be incidence of bed sore signs (e.g. local temperature) and secondary outcome will be pressure ulcer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070323035N1**
Registration date: **2015-10-31, 1394/08/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-10-31, 1394/08/09

Registrant information

Name

Fatemeh Ahmadian

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2015-06-25, 1394/04/04

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Henna (Lawsonia Inermis) on prevention of pressure ulcer

Public title

Effectiveness of Henna (Lawsonia Inermis) on prevention of pressure ulcer on hospitalized patients in Intensive Care Units

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria : No having pressure ulcer on recruitment; to be hospitalized in ICU; no diabetes; Exclusion Criteria : No desire to continue the study;

death

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

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

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Arak University of Medical Sciences, Basij Sq.

City
Arak

Postal code

Approval date
2015-06-20, 1394/03/30

Ethics committee reference number
IR.ARAKMU.REC.1394,36

Health conditions studied

1

Description of health condition studied
pressure ulcer

ICD-10 code
l89

ICD-10 code description
Decubitus ulcer and pressure area

Primary outcomes

1

Description
Sacrum local tempereture

Timepoint
every day at 10 o’clock up to one week

Method of measurement
Skin Thermometer

Secondary outcomes

1

Description
Pressure Ulcer

Timepoint
At the first day of study and after One week

Method of measurement
Braden Scale

Intervention groups

1

Description
Intervention Group: In intervention group, beside of massage of sacrum, at one time Henna is placed 15 cm on sacrum and after 30 minutes it will be washed. Then sacrum will be assessed for pressure ulcer signs (e.g. local temperature) at 10 o’clock every day up to one week.

Category
Prevention

2

Description
Control Group: In control group only routine nursing care (massage with no material) will be done. Then sacrum will be assessed for pressure ulcer signs (e.g. local temperature) at 10 o’clock every day up to one week.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Haspital

Full name of responsible person
Fatemeh Ahmadian

Street address
Alzahra Haspital, Sofeh Bl, Kheshvary High way

City
Esfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Fatemeh Ahmadian
Street address
Arak University of Medical Sciences, Basij Sq.
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Arak 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
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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