Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Henna (Lawsonia Inermis) on Pressure Ulcer Grade One in ICU Patients

Protocol summary

Summary

(1) Objectives: the purpose of this study was to examine the effect of henna on pressure ulcer grade one in ICU patients. (2) Study design: In this clinical trial, 76 patients were divided randomly into two control and intervention groups. (3) Setting and conduct: the classification form of the International Pressure Ulcer Advisory Panel was used to identify grade one ulcers. Data was collected on the first day through demographic information questionnaire and Braden pressure ulcer risk assessment scale. An infrared thermometer was used to record local temperature of the ulcers on a daily basis. Assessments were made based on Pressure Ulcer Scale for Healing (PUSH tool) and the pressure ulcer area was examined per square centimeter on the first, fourth and seventh days. (4) The participants were eligible patients hospitalized in hospitals of Isfahan University of Medical Sciences. Inclusion criteria: No history of disease and skin irritation, any food and medicine allergies, non-addiction to drugs. Exclusion criteria: Unwillingness of patients or their families to participate in the study. (5) Interventions: pressure ulcer caring methods such as repositioning was performed by nurses for all patients at least every two hours. A mixture of henna and distilled water was applied topically in the intervention group. (6) The variables included pressure ulcer assessment according to Pressure Ulcer Scale for Healing (PUSH tool), local temperature of the ulcer and pressure ulcer area per cm2.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201605167391N4**
Registration date: **2017-06-20, 1396/03/30**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2017-06-20, 1396/03/30

Registrant information

Name

Maryam Eghbali Babadi

Name of organization / entity

Isfahan University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

research deputy of Isfahan University of Medical Sciences

Expected recruitment start date

2017-01-25, 1395/11/06

Expected recruitment end date

2017-05-20, 1396/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Henna (Lawsonia Inermis) on Pressure Ulcer Grade One in ICU Patients

Public title

The effect of henna(lawsonia inermis) on pressure ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: No history of disease and skin irritation, any food and medicine allergies; non-addiction to drugs. Exclusion criteria: Unwillingness of patients or their families to participate in the study.

Age
From **18 years** old to **100 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

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
Isfahan University Of Medical Science

Street address
Isfahan University Of Medical Science, Hezar Jerib Avenue, Isfahan, Iran.

City
Isfahan

Postal code

Approval date
2017-01-25, 1395/11/06

Ethics committee reference number
IR.MUI.REC.1395.3.783

Health conditions studied

1

Description of health condition studied
Stage I decubitus ulcer

ICD-10 code
L89.0

ICD-10 code description
Stage I decubitus ulcer and pressure area

Primary outcomes

1

Description
pressure ulcer area

Timepoint
on the first, fourth and seventh days

Method of measurement
per square centimeter by meter

2

Description
local temperature of the ulcer

Timepoint
on the first, fourth and seventh days

Method of measurement
cantigrad by infrared thermometer

3

Description
Assessment of Ulcer

Timepoint
on the first, fourth and seventh days

Method of measurement
PUSH tool base on score of 0 to 17

Secondary outcomes

1

Description
allergic reaction to henna

Timepoint
Before intervention

Method of measurement
to test the allergic reaction to henna, a mixture of 1 g henna and 10 ml distilled water was applied on the inner part of the forearm to see an allergic reaction in 10 minutes

Intervention groups

1

Description
In the intervention group,pressure ulcer caring methods such as repositioning at least every two hours and keep the skin clean was performed by nurses.Then mixture of henna and distilled water was applied on the ulcer for 30 minutes .Then, the area was washed with lukewarm water and dried.

Category
Treatment - Other

2

Description
In the control group, pressure ulcer caring methods such as repositioning at least every two hours and keep the

skin clean was performed by nurses.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Azahra Hospital

Full name of responsible person

Street address

City

Isfahan

2

Recruitment center

Name of recruitment center

Amin Hospital

Full name of responsible person

Street address

City

Isfahan

3

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University Of Medical Science

Full name of responsible person

Mahdi Nematbakhsh

Street address

Isfahan University Of Medical Science, Hezar Jerib Avenue, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University Of Medical Science

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

Eghbali Babadi

Full name of responsible person

Maryam

Position

Academic member

Other areas of specialty/work

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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