

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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

+98 86 3417 3645

Email address

f.ahmadian@arakmu.ac.ir

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

I89

ICD-10 code description

Decubitus ulcer and pressure area

Primary outcomes

1

Description

Sacrum local temperature

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 Hospital

Full name of responsible person

Fatemeh Ahmadian

Street address

Alzahra Hospital, 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**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Ahmadian

Position

Nurse

Other areas of specialty/work**Street address**

Arak University of Medical Sciences, Basij Sq.

City

Arak

Postal code**Phone**

+98 86 3417 3645

Fax**Email**

ahmadian.2024@gmail.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Ahmadian

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Nurse

Other areas of specialty/work**Street address**

Arak University of Medical Sciences, Basij Sq.

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Fax**Email**

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Person responsible for updating data

Contact**Name of organization / entity**

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Fax**Email**

ahmadian.2024@gmail.com

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