

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Sep 2026

Effect patients and staffs education programs to prevention and treatment of pressure ulcers and pressure ulcer-related injuries in a general hospital: A cluster randomized controlled trial

Protocol summary

Summary

This study is a cluster randomized controlled trial to examine the effectiveness of multiple intervention strategy in reducing the number of patient pressure ulcer and pressure ulcer related injuries for 38 week at a general hospital in IRAN. The units (clusters) are determined by random allocation before the start of the trial for entrancing to the intervention phase at specific period of times (2 weeks). All clusters start the trial in a control phase with no intervention being delivered in any of them and then sequentially cross over from the control group to the intervention group, until all units are receiving the intervention. A pressure ulcer was defined as localized areas of tissue damage to skin and underlying soft tissue caused by sustained mechanical loading and shearing forces. Inclusion criteria: patient at risk of pressure ulcer with Braden (pressure ulcer risk assessment) scale less than 9, length of stay more than 48 hours in the intensive care unit, ventilator-dependent patients more than 3 days, no medical condition that would preclude the use of re-positioning, consent to participate in the study and exclusion criteria: length of stay less than 48 hours, medical condition that would preclude the use of repositioning. Sample size is accounted base on Woertman's study. It is estimated that a total of 1280 participants will require intervention. Intervention's study are assessment of patient with Braden scale, alarm to identify patients prone, patient education, employee education, massage local skin, wound wash regulatory, change position frequently, using wavy mattress, dressing, Daily visit wound care nurse. The primary outcomes are rate of reduction in pressure ulcer surface area and incidence of pressure ulcers in wards and Secondary outcomes are time to healing, percentage of wounds healed, incidence of new pressure ulcers, pressure ulcer prevalence, Grades of new pressure ulcers and length of stay.

General information

Acronym

prevention from pressure ulcer

IRCT registration information

IRCT registration number: **IRCT2016042522333N3**

Registration date: **2016-05-08, 1395/02/19**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-08, 1395/02/19

Registrant information

Name

zhila Najafpour

Name of organization / entity

Tehran University of Medical Sciences

Country

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Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Endocrinology and Metabolism Clinical Sciences Institute affiliated of Tehran University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect patients and staffs education programs to prevention and treatment of pressure ulcers and pressure ulcer-related injuries in a general hospital: A cluster randomized controlled trial

Public title
Prevention and treatment of pressure ulcers

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: patient at risk of pressure ulcer with Braden (pressure ulcer risk assessment) scale less than 9; length of stay more than 48 hours in the intensive care unit; ventilator-dependent patients more than 3 days; no medical condition that would preclude the use of re-positioning, consent to participate in the study
Exclusion criteria: length of stay less than 48 hours; medical condition that would preclude the use of re-positioning

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **1280**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Endocrinology and Metabolism Clinical Sciences
Institute affiliated of Tehran University of Medical S

Street address

Endocrinology and Metabolism Clinical Sciences
Institute, Forth Floor, Shariati Hospital, North kargar
Avenue

City
Tehran

Postal code

Approval date
2016-03-02, 1394/12/12

Ethics committee reference number
IR.TUMS.EMRI.REC.1395.0051

Health conditions studied

1

Description of health condition studied

Decubitus ulcer

ICD-10 code

L89, L89.0

ICD-10 code description

Decubitus ulcer and pressure area, Stage I decubitus ulcer and pressure area, Stage II decubitus ulcer, Stage III decubitus ulcer, Stage IV decubitus ulcer, Decubitus ulcer and pressure area, unspecified

Primary outcomes

1

Description

Rate of reduction in pressure ulcer surface area, incidence of pressure ulcers

Timepoint

38 weeks

Method of measurement

Checklist, Patient Visit, Screening of Medical Record

Secondary outcomes

1

Description

Time to healing, Percentage of wounds healed, Incidence of new pressure ulcers, Pressure ulcer prevalence, Grades of new pressure ulcers, length of stay

Timepoint

38 weeks

Method of measurement

patient visit, screening of medical record

Intervention groups

1

Description

Assessment of patient with Braden scale, alarm to identify patients prone, patient education, employee education, massage local skin, wound wash regulatory, change position frequently, using wavy mattress, dressing, Daily visit wound care nurse.

Category

Prevention

2

Description

Participants in the control phase receive usual care of hospital that consists of assessment of patients and wound dressing by nurse.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Dr.Mohamad Reza Jafari

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Endocrinology and Metabolism Clinical Sciences
Institute affiliated of Tehran University of Medical S

Full name of responsible person

Dr.Mohammad reza Mohajeri

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Endocrinology and Metabolism Clinical Sciences Institute
affiliated of Tehran University of Medical S

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

Endocrinology and Metabolism Clinical Sciences
Institute

Full name of responsible person

Dr.Hossein Adibi

Position

Assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Zhila Najafpour

Position

PHD Health Care Managment

Other areas of specialty/work

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Person responsible for updating data

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Position

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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