

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Nursing Recommendation of National Pressure Ulcer Advisory Panel on Prevention of Medical device-related pressure injury in Intensive Care Unit of Qazvin velayat Hospital

Protocol summary

Study aim

Effectiveness of Implementing the Nursing Recommendation of the International Association of Acute Wounds in Preventing Acute Injuries Due to Medical Equipment

Design

The clinical trial has a control group with 60 samples in the control group and 60 samples in the comparison group. It is a quasi-experimental study because it is not possible to randomize

Settings and conduct

In the ICU of Qazvin hospital in two groups of control and intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: log in informed consent of the patient or his family to participate in the research; Have at least one medical device connected to the patient. No entry criteria: reluctance to participate in research; restrictions on examining the skin under the device attached to the patient, for example examining the skin under the neck in patients with limited neck movement; if the equipment is removed within the first 24 hours, the patient is transferred to the ward or dies

Intervention groups

In the first phase of the study conducted in the control group, you can use your specialist doctor to eliminate and be able to use your doctor. In the second phase, which is done in the intervention group, you can have daily and using medical services you can send your letters.

Main outcome variables

Reducing the incidence of compression injuries caused by medical equipment in hospitalized patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200726048208N1**

Registration date: **2020-08-05, 1399/05/15**

Registration timing: **prospective**

Last update: **2020-08-05, 1399/05/15**

Update count: **0**

Registration date

2020-08-05, 1399/05/15

Registrant information

Name

Lida Shamekhi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3322 3973

Email address

shamekhi1367@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-09, 1399/05/19

Expected recruitment end date

2020-09-09, 1399/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Nursing Recommendation of National

Pressure Ulcer Advisory Panel on Prevention of Medical device-related pressure injury in Intensive Care Unit of Qazvin velayat Hospital

Public title

Effectiveness of Nursing Recommendation of National Pressure Ulcer Advisory Panel on Prevention of Medical device-related pressure injury in Intensive Care Unit of Qazvin velayat Hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent of the patient or his family to participate in the research. Have at least one medical device attached to the patient

Exclusion criteria:

Restrictions on examining the skin under the device attached to the patient, for example, examining the skin under the neck in a patient with limited neck movement. Reluctance to participate in research If the equipment is removed within the first 24 hours, the patient is transferred to the ward or dies

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Qazvin University of Medical Sciences, Bahonar St.

City

Qazvin

Province

Qazvin

Postal code

3413635595

Approval date

2020-03-06, 1398/12/16

Ethics committee reference number

IR.QUMS.REC.1398.379

Health conditions studied

1

Description of health condition studied

Compression injury caused by medical device

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pressure injury

Timepoint

Interval 24 hours to 21 days

Method of measurement

Scale grading pressure ulcer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The second phase of astrology is performed one week after the first phase and in the same section in the intervention group. At this stage, 60 patients who meet the inclusion criteria will be examined. For this purpose, a checklist of demographic characteristics is completed for each patient and then a checklist of medical equipment will be completed and the type of equipment will be specified. The intervention will be implemented in accordance with the recommendation that this nursing recommendation of the International Association of Acute Wounds in the prevention of compression injuries caused by medical equipment includes seven clauses, which include: 1) choosing the appropriate size of medical equipment appropriate to the person, 2) use Preventive dressings in high-risk areas, 3) Evaluate the skin area in contact with medical equipment, 4) Avoid placing equipment At the site of previous injuries, 5) Inform skin edema under medical equipment, 6) Educate staff on the proper use of medical equipment and injury prevention, and 7) Avoid contact of objects and equipment left in bed and chairs with patient skin. is. For ease of implementation, the nursing referral letter will be planned and implemented in three steps. These steps include 1) staff training, 2) comprehensive skin monitoring, and 3) preventative

dressing. The first step is to train the staff. In this regard, immediately after the sampling of the comparison group, the researcher conducted a two-hour training session for the nurses of the ICU of the provincial hospital in the field of prevention of pressure injury caused by medical equipment in PowerPoint format. Will provide this if they need more training. It was possible that this training will be done in the ICU itself according to the conditions of the patients in the ICU ward where it is not possible for all staff to leave the ward. Ways to prevent this type of injury are in line with the International Wound Association Nursing Recommendation. In order to perform the comprehensive skin monitoring step, the researcher will monitor the skin and equipment three times in 21 days in accordance with checklist number two, and in the preventive dressing step, the researcher will perform preventive dressing three times a day for 21 days. The pad will be used at the point of contact of the equipment with the patient's skin. Throughout the intervention, the assessment according to checklist number one by the researcher continues for 21 days or until the patient suffers from pressure injury caused by medical equipment (the study range is from 24 hours to 21 days). In the event of compressive injury, a calibration tool is used to determine the severity of the injury

Category

Prevention

2

Description

Control group: The first phase of the study will be conducted in a comparison group. At this stage, 60 patients with inclusion criteria (based on the number obtained from the sample size formula) will be examined. For this purpose, a demographic profile checklist is completed for each patient, and then a medical equipment checklist will be completed and the type of equipment will be specified (checklist number one). This examination begins when the patient is connected to the equipment and the daily assessment is performed by the researcher in the morning shift for 21 days (47) or until the patient suffers from compression injury caused by medical equipment and at any time the pressure injury caused. The severity of the injury was determined from the medical equipment based on the wound severity rating instrument (the study range is from 24 hours to 21 days).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin University of Medical Sciences

Full name of responsible person

Lida Shamkhi

Street address

Qazvin University of Medical Sciences, Bahonar St.

City

Qazvin

Province

Qazvin

Postal code

3416335595

Phone

+98 28 3322 3973

Email

shamekhi1367@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mehdi Imam Juma

Street address

Qazvin Valiasr crossroads. Shahid Beheshti boulevard. Abdolrazaghi branch.

City

Qazvin

Province

Qazvin

Postal code

3419915315

Phone

+98 28 3333 6001

Email

research.dpt@qums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for Research, Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

lida shamekhi

Position

nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Qazvin University of Medical Sciences, Bahonar St.

City

qazvin

Province

Qazvin

Postal code

3413635595

Phone

+98 28 3322 3973

Email

shamekhi1367@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

farnoosh rashvand

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

Street address

Qazvin University of Medical Sciences, Bahonar St.

City

Qazvin

Province

Qazvin

Postal code

3413635595

Phone

+98 28 3333 6001

Fax**Email**

n.rashvand@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Lida Shamekhi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Qazvin University of Medical Sciences, Bahonar St.

City

Qazvin

Province

Qazvin

Postal code

3413635595

Phone

+98 28 3322 3973

Fax**Email**

Shamekhi1367@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available