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Efficacy of securing urinary catheter in the reduction of urinary tract infections in the critical patients

Submission date
02/11/2023

Recruitment status
No longer recruiting

Registration date
06/11/2023

Overall study status
Completed

Last Edited
06/11/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Clinical guidelines for preventing urinary tract infections related to catheters suggest securing urinary catheters for critically ill patients, even though there is limited research on how well this works. This study's goal is to investigate if properly securing a urinary catheter can lower the chances of getting a urinary tract infection from the catheter and prevent any injuries around the urinary meatus in patients in the intensive care unit.

Who can participate?
Patients aged 18 years and above who are admitted to the Intensive Care Unit (ICU) and are expected to need a urinary catheter for more than 48 hours during their stay in the ICU. The catheter should be put in either in the ICU or the operating room, and the patient must have given their informed consent by signing a document.

What does the study involve?
In the intervention group, the urinary catheter is secured to the thigh using an in-house device, it means that H-shaped pieces of tape must be cuted. A team of 6 nurses are needed so as to control involved patients.

What are the possible benefits and risks of participating?
Patients in the intervention group may experience some discomfort related to the adhesive.

Where is the study run from?
Universitat Internacional de Catalunya (Spain)

When is the study starting and how long is it expected to run for?
July 2017 to June 2021

Who is funding the study?
This study was granted by the Sociedad Española de Enfermería Intensiva y Unidades Coronarias (Spain)

Who is the contact?
Neus Calpe Damians, neuscalpe@uic.es

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
BSI2018-19.01

Study information

Scientific Title
Effectiveness and safety profile of a simple catheter securement device aimed at preventing catheter-associated urinary tract infection in intensive care unit patients

Study objectives
Securing urinary catheter to the thigh decreases the incidence of catheter-associated urinary tact infection, as well as injuries to the meatus.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 06/02/2018, Ethical Committee of the Universitat Internacional de Catalunya (C/ de Josep Trueta, Sant Cugat del Vallès, 08195, Spain; +34 935 04 20 00; nnogales@uic.es), ref: INF-218-01

2. approved 04/07/2017, Ethical Committee of the Hospital Universitari General de Catalunya. (C /Pere i Pons, 1, Sant Cugat del Vallès, 08195, Spain; +34 935656000; mgranados@quironsalud. es), ref: 2017/03-INF-HUGC

Study design
Multicenter interventional non blinded randomized clinical trial

Primary study design
Interventional

Study type(s)
Prevention, Safety, Efficacy

Health condition(s) or problem(s) studied
Catheter Associated Urinary Tract Infetion (CAUTI)
Meatal Pressure Injuries

Interventions
Patients in the Control Group received care as usual, which included non-securement of the urinary catheter. In the Intervention Group, the urinary catheter was secured to the thigh using a simple in-house adhesive device made with a piece of adhesive tape cut in the form of an H, adapted for female and male patients, enabling the catheter to be secured without it resting directly against the skin, that was piloted as part of the present study. Alcohol-free barrier film spray was applied to prevent Medical Adhesive Related Skin Injuries, as described above. The exact site of securement was determined with the patient's leg bent, leaving sufficient slack to avoid traction with posterior movements. The date of securement was written manually on the device, which was replaced every 72 hours, or sooner if necessary.

The patient’s participation in the trial ended when one or more of the following circumstances happened: after 30 days of catheterisation, if a CAUTI was diagnosed, 48 hours after catheter removal, 48 hours after ICU discharge or in the event of death.

Patients were included using non-probability consecutive sampling and were randomised 1:1 to either the Intervention Group or Control Group using the RANDOMIZER® online tool.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Urinary catheter securement device

Primary outcome(s)
Catheter-associated Urinary Tract Infection measured every 12 hours. A urinary Tract Infection was diagnosed according to the criteria of the European Centre for Disease Prevention and Control, namely at least one of the following symptoms with no other recognised cause: fever (> 38 °C), urgency, frequency, dysuria or suprapubic tenderness – and a positive urine culture, i.e. ≥ 105 microorganisms per ml of urine with no more than two species of microorganisms. Data from this variable were collected reviewing patient notes.

Key secondary outcome(s))
Meatal pressure injury categorized according to the 1–4 grade classification system of the EPUAP–European Pressure Ulcer Advisory Panel. Data from this variable were collected by direct observation every 12 hours.

Completion date
01/06/2021

Eligibility

Key inclusion criteria
1. Age >18 years
2. Expected duration of the urinary catheter and length of stay in the intensive care unit >48 hours
3. Urinary catheter inserted in the intensive care unit or in the operating room
4. Signed informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
350

Key exclusion criteria
1. Securing not possible
2. Urinary infection or suspicion on admission
3. Allergy to adhesive tape
4. Urinary or prostatic pathology

Date of first enrolment
01/09/2017

Date of final enrolment
20/02/2020

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitari General de Catalunya
C/Pere i Pons, 1
Sant Cugat del Vallès
Spain
08195

Study participating centre
Hospital Parc Salut Mar
Passeig Marítim de la Barceloneta, 25, 29,
Barcelona
Spain
08003

Sponsor information

Organisation
Universitat Internacional de Catalunya

ROR
https://ror.org/00tse2b39

Funder(s)

Funder type
Research organisation

Funder Name
Sociedad Española de Enfermería Intensiva y Unidades Coronarias (Spanish Society of Intensive Care and Coronary Care Nurses)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the study will be avaliable upon request from Neus Calpe (neuscalpe@uic.es)

IPD sharing plan summary

Available on request