

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/11/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/11/2023	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 cut. 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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 tract 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention, Safety, Efficacy

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Urinary catheter securement device

Primary outcome measure

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 ($> 38^{\circ}\text{C}$), 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.

Secondary outcome measures

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.

Overall study start date

01/07/2017

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

100 Years

Sex

Both

Target number of participants

598

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,

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Sponsor information

Organisation

Universitat Internacional de Catalunya

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Sponsor type

University/education

Website

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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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/01/2024

Individual participant data (IPD) sharing plan

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

IPD sharing plan summary

Available on request