

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

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<b>Registration date</b> 06/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/11/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

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 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

## **Study type(s)**

Prevention, Safety, Efficacy

## **Health condition(s) or problem(s) studied**

Catheter Associated Urinary Tract Infection (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.  $\geq$  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

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## 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 available upon request from Neus Calpe (neuscalpe@uic.es)

## **IPD sharing plan summary**

Available on request