ADHESIVE DEVICES VERSUS ELASTIC DEVICES FOR URINARY CATHETER SECUREMENT IN CRITICALLY ILL PATIENTS. EXPERIMENTAL STUDY

PATIENT INFORMATION SHEET AND INFORMED CONSENT

Code: IIBSP-DAE-2025-22
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PATIENT INFORMATION SHEET

STUDY TITLE: Adhesive Devices versus Elastic Devices for Urinary Catheter Securement in Critically Ill Patients. Experimental Study
STUDY CODE: IIBSP-DAE-2025-22
SPONSOR: Research Institute of the Hospital de la Santa Creu i Sant Pau – IIB Sant Pau
SPONSOR: IR Hospital de la Santa Creu i Sant Pau

PRINCIPAL INVESTIGATOR CONTACT DETAILS:

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- Center: Hospital de la Santa Creu i Sant Pau

INTRODUCTION:

We are reaching out to inform you about a research study in which you are invited to participate. This study has been approved by the Research Ethics Committee of the Hospital de la Santa Creu i Sant Pau.

Our goal is to provide you with accurate and sufficient information so that you can decide whether or not to participate. Please read this information sheet carefully, and we will clarify any questions you may have.
You may also consult with anyone you consider appropriate.

VOLUNTARY PARTICIPATION

You are being invited to take part in this study because you have been admitted to the Intensive Care Unit (ICU) and currently have an indwelling urinary catheter.
Please note that your participation in this study is entirely voluntary, and you may choose **not** to participate. If you decide to take part, you may withdraw your consent at any time, without affecting your relationship with your doctor or the quality of your medical care in any way.

STUDY OBJECTIVE

You are invited to participate in a study aimed at improving how urinary catheters (UC) are secured in patients admitted to the Intensive Care Unit (ICU).
Below, you will find clear and simple information about what the study involves and what is expected of you.

We aim to determine whether two different catheter securement methods—**adhesive tape** or an **elastic band**—lead to fewer complications such as infections, skin injuries, or discomfort.

The main question is: **Which of the two methods is safer and more comfortable for the patient?**

STUDY DESCRIPTION

This study is intended for adult patients (aged 18 years or older) who are admitted to the ICU and have a urinary catheter in place.
We plan to recruit approximately **188 participants**.

Upon inclusion in the study, you will be randomly assigned (like a lottery) to one of two groups:

- **Group A**: adhesive securement
- **Group B**: elastic band securement

Neither you nor the healthcare team will know in advance which group each patient is assigned to, in order to ensure impartiality.

STUDY PROCEDURES

Your participation will begin on the day of inclusion and continue until your ICU stay ends or the urinary catheter is removed. If applicable, an additional 48-hour follow-up may be conducted.

A member of the research team will visit you daily at your ICU bedside to carry out the following procedures, which go beyond standard care:

- **Inspection of the securement and skin**: the device and the condition of the skin where it is attached will be checked.
- **Discomfort assessment**: you will be briefly asked if you feel any pain or discomfort due to the catheter securement.

If, at the time of your inclusion, you are wearing a different type of securement device than the one assigned through randomization, it will be replaced with the appropriate device.

No additional tests or transfers beyond standard ICU care will be required at any time.

Your responsibilities during the study include:

- Attending the daily visits
- Informing the research team of any discomfort, changes in your health, or treatments
- Not changing your treatment without consulting the study physician, except in urgent situations

RISKS AND DISCOMFORTS ASSOCIATED WITH PARTICIPATION

Both adhesive securement and elastic band securement are already commonly used in clinical practice; this study aims to confirm which method poses fewer risks.
Possible side effects include:

- Skin irritation or redness
- Minor wounds or localized pain around the securement area
- In rare cases, catheter obstruction or accidental dislodgement

There may also be unknown risks. Study-related visits may take a few extra minutes for assessments, but no invasive procedures will be performed.

POSSIBLE BENEFITS

You may not receive any **direct personal benefit** from participating in this study. However, your participation contributes to the overall benefit of improving the quality of care for ICU patients in general.
The results of this research may help nurses enhance care practices and improve patient safety.

ALTERNATIVE TREATMENTS

If you choose not to participate, you will continue to receive the same standard care provided in the ICU, including urinary catheter securement according to your hospital's usual protocol.

PROTECTION OF PERSONAL DATA

The processing, communication, and handling of personal data of all study participants will comply with **Regulation (EU) No. 2016/679** and **Organic Law 3/2018**, of December 5, on the Protection of Personal Data and Guarantee of Digital Rights.

Both the study center and the sponsor are responsible for the processing of your data and are committed to complying with the applicable data protection regulations.
The data collected for the study will be identified by a **code**, and only the principal investigator and authorized study staff will be able to link that code to your personal identity and medical records.

Your identity will **not be revealed** to anyone, except in cases of medical emergency or legal requirement.

Access to your personal information will be restricted to the study physician and collaborators, health authorities, the Research Ethics Committee, and authorized personnel from the sponsor

(such as study monitors or auditors), when necessary to verify the accuracy of the data and procedures—always maintaining confidentiality in accordance with current legislation.

According to data protection laws, you have the right to access, correct, oppose, and delete your personal data. You may also limit the use of incorrect data, request a copy, or transfer the data you provided to a third party (data portability).
To exercise your rights, you may contact the principal investigator or email the Data Protection Officer at the center: **dpd@santpau.cat**.

If you withdraw your consent to participate in the study, no new data will be added to the database. However, please note that previously collected data cannot be deleted, as it is necessary to maintain the integrity of the research and meet legal obligations.

The investigator and sponsor are required to retain the data collected for at least **25 years** after the study concludes. After that period, your personal information will only be kept for healthcare purposes and, if you have given consent (or if allowed by law and ethical standards), for further scientific research.

If coded data are transferred outside the EU to collaborators, service providers, or affiliated research institutions, your data will be protected by appropriate safeguards, such as contracts or mechanisms approved by data protection authorities.
If you would like more information, you may contact the principal investigator or the sponsor's Data Protection Officer at: **dpo_ir@santpau.cat**

EXPENSES AND FINANCIAL COMPENSATION

The sponsor of the study is responsible for managing its funding. To carry out the study, the sponsor has signed a contract with the hospital where the research will take place.

You will **not have to pay** for any products or procedures related to the study.
Your participation **will not involve any additional cost** beyond standard clinical care.
You will **not receive any financial compensation** for participating.

POST-STUDY CARE

Once your participation in the study has ended, your usual medical care will continue as indicated by your attending doctors and nurses.

OTHER RELEVANT INFORMATION

If any new information becomes available during the study that could affect your decision to participate, it will be communicated to you as soon as possible by the research nurses.

Please note that you may be **excluded from the study** if the sponsor or investigators consider it necessary, either for safety reasons or due to non-compliance with study procedures. In any case, you will be given a proper explanation for your withdrawal from the study.

INFORMED CONSENT

STUDY TITLE: ADHESIVE DEVICES VERSUS ELASTIC DEVICES FOR SECURING THE URINARY CATHETER IN CRITICAL PATIENTS. EXPERIMENTAL STUDY

I, …… (full name of participant)

- I have read the information sheet provided about the study.
- I have had the opportunity to ask questions about the study.
- I have received sufficient information about the study.
- I have spoken with …….. (full name of investigator).

I understand that my participation is voluntary.
I understand that I can withdraw from the study:

- At any time.
- Without having to give any explanation.
- Without this affecting my medical care.

I freely give my consent to participate in the study and authorize access to and use of my data under the conditions detailed in the information sheet.

Contact phone or email: ……

I will receive a signed and dated copy of this informed consent document.

Participant's signature: .....
Date: .....

Investigator's signature: .....
Date: .....

INFORMED CONSENT

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I, (full name) ……., in my capacity as (relationship to participant) …… of (full name of participant) ……..

- I have read the information sheet provided.
- I have had the opportunity to ask questions about the study.
- I have received sufficient information about the study.
- I have spoken with:
  .....
  (full name of investigator)

I understand that the patient's participation is voluntary.
I understand that they can withdraw from the study:

1. At any time.
2. Without having to give any explanation.
3. Without this affecting their medical care.

- In my presence, all relevant information adapted to their level of understanding has been provided to (name of participant) ……., and they agree to participate.
  I give my consent for (name of participant) to participate in this study and authorize access to and use of their data under the conditions detailed in the information sheet.

I wish to be informed of study results:
YES ☐ NO ☐

Contact phone or email: ……

Representative's signature: .....
Date: .....

Investigator's signature: .....
Date: .....