

# PRELIMINARY RESULTS OF A RANDOMIZED COMPARATIVE MIXED-METHOD STUDY WITH THE NEW T-CONTROL® CATHETER

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## Introduction

This is the **first clinical trial with T-Control®**, a novel silicone Foley catheter with an integrated fluid control valve. Its design aims to reduce the risks and adverse effects associated with bladder catheterisation.

The **general purpose** of this study is to **determine the effectiveness of T-Control® and the experience of the patient catheterised with T-Control® compared to the conventional Foley catheter**, by evaluating patients with long-term catheterization. A full description of the study protocol is available and published (1).

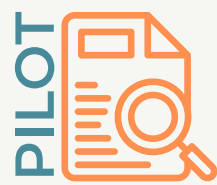


(1) Medina-Polo J, Salamanca-Castro AB, Ramallo-Fariña Y, Mòdol-Vidal M, Valcárcel-Nazco C, Armas-Moreno C, Perestelo-Pérez L, García-Pérez L, García-Bello MÁ, Luque-González M, Serrano-Muñoz M, Pérez-García S. A study protocol of a comparative mixed study of the T-Control catheter. BJUI Compass. 2024 Jan 2;5(3):345-355. <https://doi.org/10.1002/bco2.313>

How to use T-Control®



## Methods



**MIXED-METHOD TWO-ARM/PARALLEL GROUP COMPARATIVE DESIGN**

**RANDOM ALLOCATION 1:1**



**T-CONTROL® INTERVENTION GROUP N=5**



**FOLEY CONTROL GROUP N=6**

**PARTICIPATION LASTS FOR**

**4 WEEKS**

+ follow-up visit during which the study catheter is removed.

15 subjects were **recruited**. 11 subjects were included in the analysis of the quantitative primary outcome.



**ELIGIBLE PATIENTS:**  
LONG-TERM CATHETERIZATION  
who require a urinary catheter change



≥18 years

### PRIMARY ENDPOINTS

**Quantitative:** The quality of life related to self-perceived health.

**Qualitative:** The comfort and acceptability of the T-Control® device.

**Obtained through:**

- EuroQol-5D-5L.
- Catheter-related Quality of Life (QoL) questionnaire.

Both instruments are administered at patient inclusion (baseline data; day 0) and at the end of the patient's study participation (day 28).

## Results

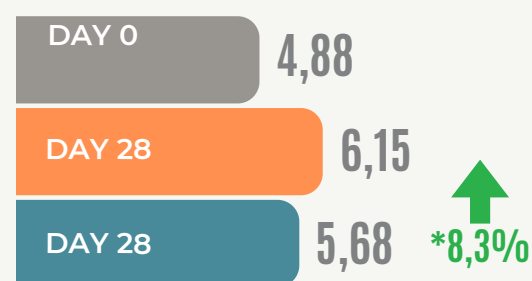
Legend

● Average of T-Control® & Foley groups

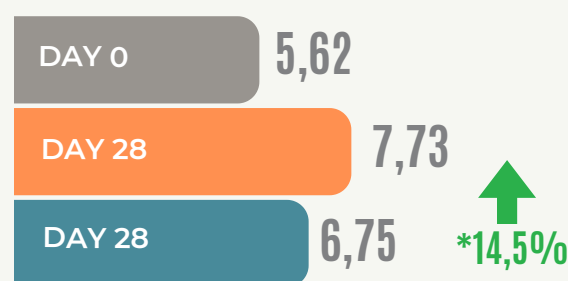
● T-Control® group

● Foley group

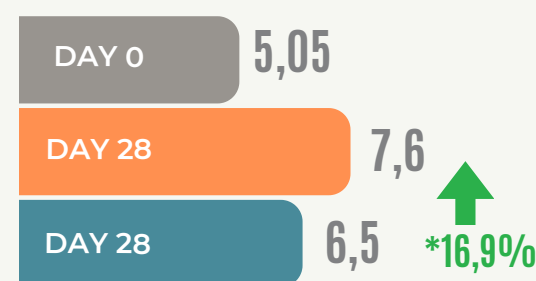
### OVERALL QOL



### POSITIVE IMPACT ON LIFESTYLE



### SATISFACTION WITH THE CATHETER



\*Difference between T-Control® and Foley  
\*\* Score from 1 to 10 (with 1 being the lowest and 10 being the highest)

Remarkably, no adverse effects have been reported in the intervention arm of the study.

## Conclusions

The preliminary results of the study indicate a **positive trend in quality of life improvements** that the new **T-Control®** device can offer to **patients with long-term bladder catheterization**. This trend is observed particularly evident in the **reduced impact on lifestyle, greater satisfaction with the device and, also a slight improvement in self-perception related to having a urinary catheter**.