

# Pilotstudy with prototype of Casto Button for catherisable urinary stomas

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Is the Casto Button an easy to use, comfortable device capable of preventing stenosis in patients with CS?

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bladder and bladder neck disorders (excl calculi)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON50241

### Source

ToetsingOnline

### Brief title

Pilot Casto Button

### Condition

- Bladder and bladder neck disorders (excl calculi)
- Cornification and dystrophic skin disorders

### Synonym

scarring, stenosis

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** catherisable stoma

## Outcome measures

### Primary outcome

Study parameters are the outcomes of the questionnaire: stenosis, leakage, fall out of the Casto Button, ability to catheterise, skin problems, overall satisfaction with the device.

### Secondary outcome

not applicable

## Study description

### Background summary

In patients who are not able to empty the bladder properly, in selected cases a catheterisable stoma (CS) is created made of appendix, ileum or bladder wall. The CS is inserted in the bladder with a valve, and to other end it is fixated in the skin of the right lower abdomen or in the umbilicus. Four to 8 times a day the bladder is emptied by inserting a catheter through the CS into the bladder. In the University Medical Center Utrecht, more than 50 adult patients with CS are under surveillance. The conjunction between stoma and skin has a tendency to become stenotic. Stenosis of the skin accounts for a high surgical revision rate. For prevention of stenosis, an ACE stopper is commonly used.<sup>1</sup> Disadvantages of the ACE-stopper include allergy, falling out, and insufficient prevention of stenosis. The ACE stopper needs to be removed before catheterization.

In cooperation with the Department of Medical Technology and Clinical Physics, a new device was developed to prevent stenosis of the skin in patients with CS. The prototype is made of titanium. Prototypes with different diameters were made for a try out.

The goal of this study is to evaluate the use of the Casto Button in a small group of patients with help of a self-developed questionnaire. Based on the results of the questionnaire, adjustments to the Casto Button can be made.

### Study objective

Is the Casto Button an easy to use, comfortable device capable of preventing stenosis in patients with CS?

### **Study design**

Patients with a CS in the lower right abdomen who are under surveillance in the University Medical Center Utrecht will be asked to participate.

After informed consent, they will be invited for a visit to determine the proper size of the Casto Button and fill out a baseline self-developed questionnaire. A sterile prototype Casto Button will be provided on loan, and oral and written instructions for use will be given. After 4 weeks the use of the Casto Button will be evaluated by a self-developed questionnaire.

### **Study burden and risks**

Catheterisable stomas of the bladder have a tendency to become stenotic at skin level. The Casto Button is designed to prevent stenosis. Patients will use a prototype made of titanium. Based on results of the questionnaire, eventual adjustments will be made and in the end a synthetic version of the Casto Button will be manufactured. So the benefit for the patient is prevention of stenosis of their catheterisable stoma. The expected risk is minimal. The burden on the patient is to fill out a questionnaire.

## **Contacts**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

18 yr or older

catherisable stoma in lower right abdomen

willing to participate

able to complete a questionnaire

### Exclusion criteria

titanium allergy

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 11-06-2018

Enrollment: 10

Type: Actual

## Medical products/devices used

Generic name:	Device For Catherisable Urinarystomas (Casto Button)
Registration:	No

## Ethics review

Approved WMO	
Date:	14-03-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	08-12-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
CCMO	NL60811.041.17