# Choice between stoma and neobladder after bladder removal for bladder cancer

No registrations found.

**Ethical review** Positive opinion **Status** Recruitment stopped

Health condition type -

**Study type** Interventional

# **Summary**

#### ID

NL-OMON20267

**Source** 

NTR

**Brief title** 

**DEDUCT** study

#### **Health condition**

Decision aid, Bladder cancer, Stoma, Neobladder, Cystectomy, Keuzehulp, Neoblaas, Cystectomie

## **Sponsors and support**

**Primary sponsor:** Radboud University Medical Centre, Nijmegen **Source(s) of monetary or material Support:** Dutch Cancer Society

Ipsen BV

## Intervention

#### **Outcome measures**

## **Primary outcome**

- \* Patient knowledge on the risks and benefits of stoma and neobladder
- \* Decisional Conflict score

## Secondary outcome

Treatment choice (stoma or neobladder)Perceived role in decision Satisfaction

# **Study description**

## **Background summary**

After bladder removal for bladder cancer, urine needs to be diverted by a stoma or a neobladder. Each option has different pros and cons for quality of life. Current guidelines ask for patient involvement in this decision. To help patients and their doctors to reach a treatment choice that best fits the individual patient, a decision aid is developed and evaluated.

## Study objective

Decision aid will increase patient knowledge and reduce decisional conflict compared to usual care

## Study design

Questionnaires were filled out after the decision was made, but before cystectomy took place

#### Intervention

Patients who had a choice between a stoma and a neobladder were presented with a webbased decision aid. Patients filled out a questionnaire. Their answers were compared to those of patients receiving usual care (without decision aid).

# **Contacts**

#### **Public**

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# **Eligibility criteria**

## **Inclusion criteria**

Patients who have a choice between stoma and neobladder after cystectomy

## **Exclusion criteria**

Insufficient knowledge of the Dutch language

# Study design

## **Design**

Study type: Interventional

Intervention model: Parallel

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active

## Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-03-2016

Enrollment: 60

Type: Actual

## **IPD** sharing statement

Plan to share IPD: Undecided

## **Ethics review**

Positive opinion

Date: 29-06-2017

Application type: First submission

# **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

NTR-new NL6286 NTR-old NTR6460

Other KWF (Dutch Cancer Society): KUN 2014-6945

# **Study results**

### **Summary results**

<sup>\*</sup> van Tol-Geerdink JJ, DM Somford, C Wijburg, JA Witjes. Decision support in the choice between neobladder and stoma after bladder removal. Med Decision Making 38(6): E433, 2018

<sup>\*</sup> van Tol-Geerdink JJ, DM Somford, C Wijburg, AG van der Heijden, JA Witjes. Keuzehulp voor cystectomie patiënten: stomaofneoblaas.nl Tijdschr. Urol. 9(2), 22-30, 2019