

Urinary Tract Infections in Patients with poor bladder emptying and who use 'Intermittent Catheterisation' to self empty their bladder.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20778

Source

NTR

Health condition

Urinary Tract Infections
Intermittent Catheterisation
Urine retention
Urinary tract infections
zelfkatheterisatie
Urine retentie

Sponsors and support

Primary sponsor: Martini Hospital Groningen

Source(s) of monetary or material Support: Martini Hospital Groningen

Hollister Incorporated (unrestricted grant)

Goodlife Pharma (unrestricted grant)

Intervention

Outcome measures

Primary outcome

The incidence of UTI's in patients in Martini General Hospital Groningen and intended other (Santeon) hospitals using CIC to empty their bladder.

Secondary outcome

The impact of an UTI on patients' quality of life and on illness related (economic) costs e.g. direct costs of treatment, amount of hospital visits, hospital recording, loss of productivity etc.

Study description

Background summary

UTI's are commonly seen in CIC patients. This can have great impact on patients and healthcare spenders. However treatment and prevention of UTIs in CIC patients are largely not evidence-based.

In this multicentre prospective cohort study we aim to establish a reliable incidence number for UTIs and gain insight in the impact on patients' quality of life and on illness related (economic) costs e.g. direct costs of treatment, amount of hospital visits, hospital recording, loss of productivity etc.

Study objective

In this observation study we hypothesise an incidence of UTIs of 30% in the first year after starting CIC. Moreover we hypothesise a marked reduction in quality of life and an increase in health care expensis in patients with UTI.

Study design

1. Baseline at which patients start CIC;
2. One month follow-up;
3. Three months follow-up;
4. Twelve months follow-up.

Intervention

Contacts

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Eligibility criteria

Inclusion criteria

Patients needing CIC to empty their bladder properly (residu after voiding/retention) or needing CIC to prevent strictures of the urethra.

Exclusion criteria

1. Patients younger than 18 years;
2. Patients who are pregnant or get pregnant during the study;
3. Mentally-retarded and demented patients;
4. Patients starting with antibiotics precautionary longer than three days.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2013
Enrollment:	384
Type:	Anticipated

Ethics review

Positive opinion	
Date:	18-02-2013
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	NL3692

Register

NTR-old

Other

ISRCTN

ID

NTR3862

ABR : 43313

ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A