Urinary tract infections in patients practicing intermittent catheterization

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Research questions:* What is the incidence of UTI*s in patients in Martini General Hospital Groningen and other Santeon hospitals using CIC to empty their bladder?* What is the impact of an UTI on patients*quality of life and on illness related (...

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

Summary

ID

NL-OMON38429

Source
ToetsingOnline

Brief title
Urinary tract infections in CIC patients

Condition

- Bladder and bladder neck disorders (excl calculi)

Synonym
urinary tract infections in CIC patients and impact of UTI

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: Een unristricted grant van de firma's Hollister en GoodLife,Goodlife,Hollister

Intervention

Keyword: CIC, intermittent catheterization, urinary tract infection, UTI

Outcome measures

Primary outcome

The primary outcome is the incidence of UTI*s in CIC patients.

In the field of Urology, there is no universal consensus for the definition of UTIs However, classification of UTIs is important for clinical decisions and research.

In this study we based the definition for UTIs on the classifications of the Centres of Disease and Prevention in de USA (CDC 2008), the classification of the European Assosiation of Urology (EAU 2010) and Prezies 2012 (Dutch guidelines of hospital infections); this guideline Is also based on the CDC classifications. In fact, these definitions are rather similar and reflect the opinion of the major expert groups in this field.

The current classifications of UTIs are based on the concept of two main categories: uncomplicated and complicated UTIs. An uncomplicated UTI/asymptomatic bacteriuria (ASB) is considered not as an infection but a risk factor for a UTI.

A Symptomatic UTI is present if there are clinical symptoms indicative of UTI and if the presence of pathogens can be verified by culture or dipstick. The clinical presentation is classified as cystitis (dysuria, frequency, urgency,

suprapubic pain), pyelonefritis (fever, flank pain).

Significant bacteriuria in adults is considered * 105 uropathogens/ml in midstream urine of women or 104 uropathogens/ml of midstream urine in men with complicated UTI (EAU2012)

UTI in concrete defined in this study: the combined outcome of bacteriuria (105 CFU/ML) and pyuria (> 10 white bloodcells/mm^3) and one or more of the following symptoms; frequency, urgency, dysuria, stranguria, fever or haematuria.

Urinary analysis will be based on a reagent test and if positive (for nitrite) as well on full-microbiological analysis.

Secondary outcome

The Secondary outcomes are:

* The impact of UTI in daily life measured by questionnaire and interviews

* Self-care behaviour, measured by interviews

* Health related quality of life measured by the Rand-36 (Van der Zee 1993)

* Health-care consumption based on hospital records/patient files and a checklist for patients

Confounders are patient characteristics (e.g. gender, age, educational level), catheter type, frequence of CIC and clinical features (e.g. disease status).

All measurements (except demographics) will be done at baseline, one month, three, and twelve months follow.

Study description

Background summary

Poor bladder emptying is a well-known phenomenon in urology. Urine remaining in the bladder increases the risk of an urinary tract infection (UTI).
Effective bladder emptying therefore is essential. This may be performed by draining the bladder intermittently by means of a disposable catheter or by an indwelling catheter. The method emptying the bladder intermittently is called clean intermittent (self) catheterisation (CIC). Nowadays CIC is a commonly recommended procedure for people with incomplete bladder emptying in order to protect the bladder and renal health. It involves several times a day the insertion of a disposable catheter into the bladder, outflow of the urine and removal of the catheter. (Achterberg et al., 2006)

Urine normally does not contain microorganisms, but if urine is retained in the bladder, it provides a good environment for bacteria to grow. Although CIC insures bladder management to prevent complications as an UTI and hydronefrosis, long-term catheterization can also cause an UTI (de Ridder, 2005). For example poor maintaining of following instructions or poor hygiene can lead to bacteriuria and inflammation and subsequently pyelonefritis (Getliffe, 2006).

Bacteria growing around the meatus can be introduced into the urethra to manifest an UTI. Catheterisation can cause such introduction. The microorganisms stick to the wall of the urethra, multiplying and moving up the urethra to the bladder. Most UTI*s remain in the lower urinary tract, where they cause symptoms such as urgency and burning sensation during micturition. In general asymptomatic bacteriuria will not be treated. The blanket term UTI is frequently used, but a urinary tract infection may also be identified by the part of the urinary tract affected. Urethritis is an inflammation and/or infection of the urethra. Bladder involvement is called cystitis, and when one or two of the kidneys are inflamed or infected, it is called pyelonephritis.
In this study an UTI is defined as the combined outcome of bacteriuria (105 CFU/ML) and pyuria (> 10 white bloodcells/mm^3) and one of the following symptoms; frequency, urgency, dysuria, fever, stranguria or haematuria.

To a large extent the care for CIC patients is not evidence-based. Some studies state that hydrophilic catheters might reduce UTI*s (Jaquet, 2009). According to recent literature, approximately 30% of CIC patients get bacteriuria and 7-10% of the patients using CIC will get an UTI and need to be treated with antibiotics (Rew. 2003). However, these numbers do not seem to reflect daily

practice and underreport the number of UTI*s. For example in Martini General Hospital Groningen in the last two years, 32 % of the new CIC patients (n=123) got an UTI within 6 months after starting CIC. This high incidence means that more and more patients are treated with antibiotics by general practitioners/urologists.
To detect an UTI urinalysis is needed. The most common way to analyse urine is by means of a simple reagent strip. In this way abnormalities in the urine can be detected.
A positive nitrite test on a reagent strip indicates bacterial infection.
Pyuria also indicates bacterial infection. If there are no symptoms, antibiotics are normally not required. If systematic symptoms are present, full microbiological analysis is warranted to prescribe specific and sensitive antibiotics.

Suffering from an UTI influences patients quality of life. (Ellis. 2000). This may lead to absence of work, loss of quality of life, taking more medicine etc., resulting in more costs.

In summary, UTI*s are commonly seen in CIC patients. This can have great impact on patients and healthcare expenders. However treatment and prevention of UTI*s in CIC patients are largely not evidence-based.

Study objective

Research questions:

* What is the incidence of UTI*s in patients in Martini General Hospital Groningen and other Santeon hospitals using CIC to empty their bladder?
* What is 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 design

Study design and participants:
The study will be a prospective multi-centre observational trial. We will perform the study within the Santeon network consisting of six large, top clinical hospitals in the Netherlands (www.santeon.nl). These hospitals collaborate on multiple domains, including scientific research. We aim to include at least three other hospitals besides the Martini Hospital. In the participating Santeon hospitals a nurse (specialist) will be trained in this protocol and will locally coordinate the study. The overall coordination will be done by the coordination team in the Martini hospital.

In the participating centres, patients starting CIC will be asked to participate in the study. Patients starting CIC will receive standard care.

That is education according to the Dutch guideline (VenVN CVV; Verpleegkundigen en Verzorgenden Nederland afdeling Continentie Verpleegkundigen en Verzorgenden); association of Dutch nurses and carers department of continence-care.
Standard catheter as given in the hospital or to patients* preference. Hence different cathetertypes will be used

At baseline, and during the follow-up after one, three and twelve months an urinary analysis will be done and patients are asked to fill in a questionnaire on their health care consumption, quality of life, impact of an UTI and self care behaviour. Moreover a selection of patients will be interviewed to get a more in-depth view of their self-care and impact of the UTI (semi structured). See flowchart of research fig 1.

If there are signs of an UTI during the study, patients are asked to come to the hospital for urinary analysis and treatment if necessary.

Power and representativeness of the study population
The primary outcome measure is the occurrence of UTI*s. To assess the expected 30 % incidence of an UTI in this population with a 95% confidence interval of plus or minus 5 % a sample of 384 patients is required.
These patients are retrieved from the populations of the Santeon hospitals which account for more than 10% of the patients treated in Dutch general hospitals. The Santeon hospitals can be considered to have a representative sample of patients since they are almost non-restrictive in patient population, i.e. provide both basic hospital care and complex care. Moreover, the Santeon hospitals are geographically evenly distributed across the Netherlands in rural and urban areas.

Study burden and risks

Minimal extent of burden and risk. The care given is acording to the standard.
During the follow-up a two time more visit is necessary.
During these visits patients will be asked to fill in a questionnaire. A selection of patients will also be asked to have an interview.
Is symptoms of an UTI is present an extra visti to the hospital is necessary.

Minimale belasting. De gegeven zorg behoord tot de standaard zorg. Tijdens de follow-up zal twee keer vaker dan normaal een controle volgen. Tijdens de controle zal er een vragenlijst ingevuld dienen te worden. Bij een selecte groep patiënten zal een interview worden afgenoemn.
Bij sympotmen van een UWI zal een tussentijds bezoek aan het ziekenhuis

noodzakelijk zijn.

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

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

Exclusion criteria

patients younger than 18 years, patients who are pregnant or get pregnant during the study, mentally-retarded or demented patients, patients starting with antibiotics precautionary

longer then three days

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2013
Enrollment:	384
Type:	Actual

Ethics review

Approved WMO

Date:	06-05-2013
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Approved WMO

Date:	19-09-2013
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL43313.099.13