Implementation of a clinical decision rule to optimize hospital admission policy of patients with febrile urinary tract infection

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To validate a clinical decision rule to guide need for hospitalization in patients presenting with febrile urinary tract infection (FUTI) with the aim to reduce the hospitalization rate without compromising clinical outcome.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON41359

Source
ToetsingOnline

Brief title
Prediction rule for admission policy in complicated UTI Leiden (PRACTICE)

Condition

- Bacterial infectious disorders
- Urinary tract signs and symptoms

Synonym
febrile urinary tract infection, pyelonephritis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW doelmatigheidssubsidie;projectnr. 80-82305-97-11057,Bronovo Research Fonds

Intervention

Keyword: febrile urinary tract infection, hospitalization, outpatient treatment, prediction rule

Outcome measures

Primary outcome

The primary objective will be evaluated by primary and secondary outcome measures.

The primary outcome measure are primary hospital admission rate (i.e. the percentage of patients presenting with FUTI at ED who will directly be admitted to hospital) and secondary hospital admission rate (i.e. the percentage of low-risk patients with PRACTICE < 100 points who need to be hospitalized after initial home-based treatment). The secondary outcome measures are 30- and 90-day mortality rate, Intensive Care Unit (ICU) admission rate, the total number of hospitalization days over a 3-month follow-up and clinical- and microbiological cure rate.

Secondary outcome

The secondary outcome will be evaluated from a 3-months perspective. Costs will include the time to assess the decision rule, primary and secondary hospitalization costs, extra costs of primary care and the costs of radiologic diagnostics (as home based management might also lead to reduction in radiologic evaluations to search for underlying urologic abnormalities).

Patients* satisfaction with application of the PRACTICE will be evaluated soon

after enrolment and 1 month thereafter.

Study description

Background summary

In daily clinical practice the risk of a complicated course and thereby need for clinical observation and hospital-based treatment for febrile urinary tract infection (FUTI) is assessed on basis of history, underlying disease and on severity of local and vital signs. Fever is a sign with little specificity, and may reflect the mere presence of local kidney infection or of impending urosepsis. Prompt recognition and start of preferably intravenous antibiotic treatment of the latter condition is of utmost importance, to prevent progression to septic shock and death.
Currently, in the Netherlands about 90% of patients presenting at emergency departments with febrile UTI will be admitted, because of a low chance of life-threatening complications that cannot be reliably estimated. Clinical tools helping to classify risks in patients with febrile UTI are urgently needed and should be helpful to better identify those who benefit from hospital admission, and those who can be safely treated at home.
We recently derived and validated a clinical prediction rule that adequately predicts a complicated outcome or death in patients with FUTI. This prediction rule, called the Prediction Rule for Admission policy in Complicated urinary Tract InfeCtion LEiden (PRACTICE), is a bedside clinical score which allocates points to readily available variables including age, sex, co-morbidity and vital signs.
There is sufficient evidence that young non-pregnant women without co-morbidity are good candidates for outpatient treatment. In previous studies, we demonstrated that selected elderly, men and patients with co-morbidity might also be eligible for outpatient home-based treatment. Previous studies indicate that the costs of FUTI are most sensitive to hospitalization rates.
We assume that the PRACTICE is a good bedside clinical tool to identify low-risk patients with FUTI who can be managed as outpatients. Introduction of the PRACTICE into clinical practice may thus lead to lower hospitalization rates without compromising clinical outcome, and lower medical costs. This study, which is unique with regard to its subject and population, will evaluate this hypothesis. Known and recently identified biomarkers will be assessed to correlate to the success of application of the PRACTICE in the future.

Study objective

To validate a clinical decision rule to guide need for hospitalization in patients presenting with febrile urinary tract infection (FUTI) with the aim to

reduce the hospitalization rate without compromising clinical outcome.

Study design

A stepped wedge cluster-randomized trial. All the participating centers will start with a 3-month control period. Thereafter, every 3 months one of the centers will start with the intervention period until the end of the trial. In the end, all study sites have received the intervention.

Intervention

Use of the Prediction Rule for Admission policy in Complicated urinary Tract InfeCtion LEiden (PRACTICE) to help guide physicians. The PRACTICE-score can be divided into several risk classes.

According to risk class the following recommendations will apply:
< 75 points: strongly recommendation towards home based management
75-100 points: consider home based management
>100 points: strongly recommendation towards hospital admission

For more details about the PRACTICE, see paragraph 5.1

Study burden and risks

The burden of study procedures is limited. Besides the clinical decision rule to determine which patient to admit and which patient to refer safely back to primary care, the diagnostic and therapeutic approach to the patient will be the standard clinical practice in all study centers. Subjects are contacted twice by phone and twice in person by a home visit to evaluate their medical condition. One extra urine culture will be performed and two additional blood and urine samples will be taken. Subjects will be asked to fill a short standardized satisfaction questionnaire.
Implementation of the clinical decision rule by definition holds a risk that certain patients will initially be managed as outpatients, while at a later stage, hospitalization is deemed mandatory. Based on own experiences with home-based treatment, it is not expected that this may alter patients* clinical outcome. Furthermore, the risk of unnecessary hospitalization (e.g. hospital-acquired infections and * antimicrobial resistance) should not be underestimated.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Competent patient aged 18 years or above
2. One or more symptom(s) suggestive of urinary tract infection (UTI) (dysuria, frequency or urgency; perineal or suprapubic pain; costovertebral tenderness or flank pain)
3. Fever (ear of rectal temperature of 38.2 oC or higher, or axillary temperature of 38.0 oC or higher), or a history of feeling feverish with shivering or rigors including the past 24 hours
4. Positive urine nitrate test and/or leukocyturia as depicted by positive leukocyte esterase test or microscopy

Exclusion criteria

1. Known allergy to fluoroquinolones
2. Female patients who are pregnant or lactating
3. Patients known with polycystic kidney disease
4. Patients on permanent renal replacement therapy (hemodialysis or peritoneal dialysis)
5. Patients with history of kidney transplantation
6. Residence outside country of enrolment

7. Inability to speak or read Dutch

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-05-2012
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO Date:	11-05-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	20-02-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	18-03-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	21-05-2013

Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	27-11-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	08-10-2014
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	24-11-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25370
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL35220.058.11
OMON	NL-OMON25370

Study results

Date completed:	01-05-2016

Results posted:	25-01-2018
Actual enrolment:	420

First publication
01-01-1900