

# Prediction Rule for Admission policy in Complicated urinary Tract Infection LEiden.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25370

### Source

NTR

### Brief title

The PRACTICE study.

### Health condition

Urinary tract infections, urosepsis, acute pyelonefritis, acute prostatitis.

## Sponsors and support

**Primary sponsor:** Leiden University Medical Center (LUMC)

**Source(s) of monetary or material Support:** ZON-MW, The Netherlands Organization for Health Research and Development

## Intervention

## Outcome measures

### Primary outcome

- Primary hospital admission rate.

- Secondary hospital admission rate defined as the percentage of patients who need to be hospitalized after initially being treated at home.

### **Secondary outcome**

- Total number of hospitalization days over a 3-month follow-up
- 30-day and 90-day mortality rate
- Intensive Care Unit admission rate
- Hospitalization costs during 3-month follow-up
- Patients' satisfaction with application of the PRACTICE
- Clinical- and microbiological cure rate

## **Study description**

### **Study objective**

Introduction of the PRACTICE into clinical practice leads to lower hospitalization rates without compromising clinical outcome, and lower medical costs.

### **Study design**

Day 0, 2-4, 24-32 and 84-98.

### **Intervention**

Use of the PRACTICE to guide physicians, summing the points for each characteristic: age in years (females age-10); nursing home resident +10; malignancy +30; liver cirrhosis +20; congestive heart failure +10; cerebrovascular disease +10; renal disease +10; altered mental status +20; respiratory rate  $\geq 30/\text{min}$  +20; systolic blood pressure  $<90$  mmHg +20; pulse rate  $>124/\text{min}$  +10; temperature  $>39.9$  C +15. Recommendations:  $<75$  points: strongly recommendation towards home-based management; 75-100 points: consider home-based management;  $>100$  points: strongly recommendation towards hospital admission.

## **Contacts**

### **Public**

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## **Eligibility criteria**

### **Inclusion criteria**

1. Competent patient aged 18 years or above;
2. One or more symptom(s) suggestive of urinary tract infection (dysuria, frequency or urgency\*; perineal or suprapubic pain; costo-vertebral tenderness or flank pain);
3. Fever(ear or rectal temp of 38.2 C or higher, or axillary temp of 38 C or higher), or history of feeling feverish with shivering or rigors in the past 24 hours;
4. Positive urine nitrate test and/or leucocyturia 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 with known 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:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2012
Enrollment:	652
Type:	Actual

## Ethics review

Positive opinion	
Date:	25-03-2014
Application type:	First submission

## Study registrations

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

ID: 41359  
Bron: ToetsingOnline  
Titel:

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

No registrations found.

## In other registers

Register	ID
NTR-new	NL4340
NTR-old	NTR4480
CCMO	NL35220.058.11
OMON	NL-OMON41359

## Study results