Febrile Urinary Tract Infection Randomized Short Treatment Trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20802

Source
NTR

Brief title
FUTIRST

Health condition

urinary tarct infection, acute pyelonephritis, urosepsis

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Leiden University Medical Center

Intervention

Outcome measures

Primary outcome

The clinical cure rate through the 10- to 18-day posttherapy visit. Clinical cure is defined as the resolution of fever and signs and symptoms of UTI.

Secondary outcome

This includes microbiological cure rate 10- to 18-day posttherapy, 30- and 90- day overall mortality rate, clinical cure rate 70- to 84- day posttherapy, time to resolution of symptoms, relapse rate of UTI, adverse events or complications, rate of pelvic floor dysfunction as assessed by a standardize questionaire and the occurrence of Clostridium difficile disease.

Study description

Background summary

In the last decades hospitalization rates of patients with acute pyelonephritis (AP) or febrile urinary tract infection (FUTI) has decreased from almost 100% to 10-30%. The outpatient management of patients with FUTI has become popular as well as oral antimicrobial treatment regiments and shortening of treatment duration. However, as such approaches are only discovered in otherwise young health non-pregnant women, the best management of FUTI in the elderly, men and patients with co-morbidity remains elusive. Again, based on personal perception of the attending physician, antibiotic treatment duration varies approximately between 7-14 days. Facing the aging of the general population, it is urgent to better define the optimal treatment for AP or FUTI in an unselected population and to identify those at risk for treatment failure or poor outcome to guide and optimize individual patient management and to prevent on the one hand unnecessary long treatment duration and hospital admission and on the other hand unsafe short duration or unsafe outpatient management.
In this study the efficacy and safety of a 7-day antimicrobial regimen compared to a 14-day antimicrobial regimen will be evaluated in an unselected population presenting with FUTI at primary care or emergency department and a clinical and/or biomarker based scoring system of disease severity will be derived to predict those at risk for treatment failure or poor outcome.

Study objective

A 7-day course of antibiotic treatment is non-inferior to a 14-day course in febrile urinary tract infection.

Study design

Day 0, 3-4, 24-32 and 84-98.

Intervention

7 days of standard antiobiotic treatment (preferably ciprofloxacin) followed by 7 days of blinded oral ciprofloxacin (500 mg bid) or placebo (bid).

Contacts

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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 oC or higher, or axillary temp of 38 oC 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;

8. Isolation of causal ciprofloxacin resistant uropahtogen;

9. Presence of renal abcess, chronic bacterial prostatitis or metastatic infectiuous foci.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2008
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-12-2008
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	NL1513
NTR-old	NTR1583
Other	clinicaltrials.gov : NCT00809913
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results