Febrile Urinary Tract Infection Randomized Short Treatment Trial.

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20802

Bron
NTR

Verkorte titel
FUTIRST

Aandoening

urinary tarct infection, acute pyelonephritis, urosepsis

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Leiden University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2008
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-12-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1513
NTR-old	NTR1583
Ander register	clinicaltrials.gov : NCT00809913
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten