SPRING
Study of Prevention of Recurrent urinary tract infections by Intravesical iNstilment of Gentamicin

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Prophylaxis with intravesical overnight instillation of gentamicin reduces the number of recurrences of UTI in patients with recurrent urinary tract infections due to multi-drug resistant bacteria, as compared to oral antibiotic prophylaxis.

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

Samenvatting

ID

NL-OMON23211

Bron
Nationaal Trial Register

Verkorte titel
SPRING

Aandoening

recurrent urinary tract infections
multi-drug resistant bacteria
cystitis
prophylaxis
recidiverende urineweginfecties
multi resistente bacterieen

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of UTI per patient after start of intravesical gentamicin or oral antibiotic prophylaxis during 6 months (period of prophylactic treatment) and 12 months (total follow up)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Management of patients with recurrent urinary tract infections (UTI) is challenging, even more so in the era of rising antimicrobial resistance. Multidrug-resistance is currently leading to an increased need for intravenous treatment of UTIs with reserve antibiotics and subsequent hospitalizations. Prophylaxis with low dose oral antibiotics, as recommended by current guidelines, is often limited by multidrug-resistance of uropathogens, and if possible may even further extent the development of resistance. In such patients with recurrent UTI due to multi-drug resistant uropathogens, intravesical gentamicin installation is a potential valuable treatment option for either suppression or prevention of UTI. Locally administered aminoglycosides bypass systemic toxicity and development of antimicrobial resistance is unlikely because of high urinary levels and lack of antibiotic pressure on commensal gut flora.

Doel van het onderzoek

Prophylaxis with intravesical overnight instillation of gentamicin reduces the number of recurrences of UTI in patients with recurrent urinary tract infections due to multi-drug resistant bacteria, as compared to oral antibiotic prophylaxis.

Onderzoeksopzet

Follow up at wk 1, 2, 7-8, 12-14, 22-24, 34-36, 2 months, 3 months, 6 months, 9 months and 12 months.

Onderzoeksproduct en/of interventie

Randomization 2:2:1:

1. Intravesical installations of gentamicin during a period of 24 weeks (once daily for 2 weeks, every other day for 10 weeks, twice weekly for 12 weeks).

2. Low dose oral antibiotic prophylaxis based on prior susceptibility pattern of isolated uropathogens and patient characteristics, reflecting current standard care, for 24 weeks.

3. Wait and see policy without antimicrobial prophylaxis. In case of a first UTI after enrolment, patients will be randomized to study group 1 or 2.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Competent patient aged 18 or above.

- A history of recurrent cystitis, defined as:

a. females: at least 2 episodes of UTI in the last 6 months or 3 in the last 12 months

b. males: at least 2 episodes of UTI in the last 12 months (including recurrent cystitis likely due to chronic bacterial prostatitis).

- At least one episode of these infections is documented by urine culture with the isolation of

>10^3 CFU/mL of an identified MDR pathogen. Multidrug resistance is defined as acquired non-susceptibility to at least one agent in three or more antimicrobial classes.

- All other episodes at least by one urinary symptom* and positive urinary nitrate test or leukocyturia (as depicted by positive leukocyte esterase test or microscopy).

- No clinical symptoms of UTI at enrolment.

Ad * Definitions of urinary symptoms:

- Dysuria: pain, tingling or burning sensation in the perineum during or just after urination.

- Frequency: more than usual, abnormal, frequent voiding.

- Urgency: unusual intense and sudden desire or urge to void.

- Suprapubic and/or perineal pain.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Urinary culture in prior 6 months tested positive for high-level gentamicin resistant enterobacteriaceae or enterococci (MIC >128 mg/L).

- Abnormalities of the upper urinary tract, including presence of urinary stones.

- Patients with a permanent urinary catheter.

- Complete urinary incontinence.

- Patients with stage 5 chronic kidney disease (GFR <15 ml/min).

- Patients with known hypersensitivity to gentamicin.

- Pregnancy or lactation.

- Inability to provide informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2014
Aantal proefpersonen:	170
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	16-06-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38402
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4404

Register	ID
NTR-old	NTR4646
CCMO	NL46991.058.13
OMON	NL-OMON38402

Resultaten

Samenvatting resultaten

van Nieuwkoop C, den Exter PL, Elzevier HW, den Hartigh J, van Dissel JT. Intravesical gentamicin for recurrent urinary tract infection in patients with intermittent bladder catheterisation. Int J Antimicrob Agents. 2010 Dec;36(6):485-90