ASB treat study.

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To evaluate whether nitrofurantoin treatment for women with asymptomatic bacteriuria is effective in reducing the risk of preterm delivery and/or pyelonephritis (primary outcome) and bad neonatal outcome (secondary outcome). In addition, assessing...

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

Samenvatting

ID

NL-OMON24261

Bron
NTR

Verkorte titel
ASB-treat

Aandoening

asymptomatic bacteriuria, pregnancy, preterm birth, pyelonephritis
asymptomatische bacteriurie, zwangerschap, vroeggeboorte, nierbekkenontsteking

Ondersteuning

Primaire sponsor: AMC Amsterdam, department of Obstetrics and Gynecology
Overige ondersteuning: ZonMW 50-50110-96-530

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main primary outcomes are a composite endpoint of pyelonephritis and preterm delivery (< 34 weeks). Pyelonephritis will be defined as an episode of fever, clinical symptoms and a positive urine culture.

Toelichting onderzoek

Achtergrond van het onderzoek

Spontaneous preterm delivery is the single most important cause of perinatal mortality in the Western world. Antibiotic treatment is effective in clearing asymptomatic bacteriuria (ASB) and pyelonephritis and is associated with a reduction in the incidence of low birth weight babies. However, no study performed so far has been able to show a statistically significant effect to reduce preterm delivery and/or adverse neonatal outcome.
We want to evaluate whether nitrofurantoin treatment for women with asymptomatic bacteriuria is effective in reducing the risk of preterm delivery and/or pyelonephritis (primary outcome) and bad neonatal outcome (secondary outcome). In addition, assessing whether it is cost-effective to screen and treat for ASB

Doel van het onderzoek

To evaluate whether nitrofurantoin treatment for women with asymptomatic bacteriuria is effective in reducing the risk of preterm delivery and/or pyelonephritis (primary outcome) and bad neonatal outcome (secondary outcome). In addition, assessing whether it is cost-effective to screen and treat for ASB.

Onderzoeksopzet

Women will be screened between 16-22 weeks of their pregnancy. One week after completing their studymedication their urine will again be tested for asymptomatic bacteriuria

Onderzoeksproduct en/of interventie

Nitrofurantoine 2dd100mg for 5 subsequent days.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Capacitated women;

2. ≥18 years old;

3. Singleton healthy pregnancy;

4. Positive urine culture.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Foetal abnormalities, detected by ultrasound;

2. Signs of (threatened) preterm labor e.g. painful regular uterine contractions;

3. A history preterm labor <34 weeks;

4. A cervical cerclage in current pregnancy;

5. Symptoms of a urinary tract infection;

6. Known G6PD deficiency or known allergy to nitrofurantoin;

7. Risk factors for complicated UTI (diabetes, immunosuppressive medication, functional or structural abnormalities of the urinary tract).

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2011
Aantal proefpersonen:	320
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-09-2011
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	NL2921
NTR-old	NTR3068
Ander register	MEC AMC / Eudract : 2011-073 / 2011-000129-61;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A