ASB treat study.

No registrations found.

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

Summary

ID

NL-OMON24261

Source
Nationaal Trial Register

Brief title
ASB-treat

Health condition

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

Sponsors and support

Primary sponsor: AMC Amsterdam, department of Obstetrics and Gynecology
Source(s) of monetary or material Support: ZonMW 50-50110-96-530

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcome measure is adverse neonatal condition (death or severe morbidity). This composite morbidity rate contains the following variables: Severe Respiratory Distress Syndrome (RDS), Bronchopulmonary Dysplasia (BPD), Intraventricular Haemorrhage grade II B or worse, Necrotizing Enterocolitis (NEC), proven sepsis and death before discharge from the nursery.18 They will be measured until 10 weeks after the expected term date.

Other parameters are: Neonatal weight, time to delivery, preterm birth rate before 32 and 37 weeks, presence of chorioamnionitis, days of admission in neonatal intensive care unit, maternal morbidity (including UTI), maternal admission days for preterm labour and costs.

Moreover, we will look at growth, physical condition and neurodevelopmental outcome of the offspring at 24 months (corrected) age. If possible, we will stratify for cervical length.

Next to secondary clinical outcome, the cost-effectiveness of screening for asymptomatic bacteriuria (as done in triple P/ ASB screening), and subsequent treatment in case of ASB, will be assessed.

Study description

Background summary

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

Study objective

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.

Study design

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

Intervention

Nitrofurantoine 2dd100mg for 5 subsequent days.

Contacts

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Eligibility criteria

Inclusion criteria

1. Capacitated women;

2. ≥18 years old;

3. Singleton healthy pregnancy;

4. Positive urine culture.

Exclusion criteria

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).

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):	01-11-2011
Enrollment:	320
Type:	Anticipated

Ethics review

Positive opinion

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

Study results

Summary results
N/A