

Asymptomatic Bacteriuria and Urinary Tract Infections in pregnant women with and without Diabetes Mellitus

Published: 18-02-2009

Last updated: 05-05-2024

What is the prevalence of ASB and incidence of UTIs during pregnancy in women with DM or GDM compared to pregnant women without diabetes? In addition, risk factors for ASB and UTIs, as well as consequences of ASB and UTIs will be investigated. These...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON32590

Source

ToetsingOnline

Brief title

ASB and UTIs in pregnant women with and without DM
PRABUTI studie

Condition

- Diabetic complications
- Maternal complications of pregnancy
- Urinary tract signs and symptoms

Synonym

bacteriuria, Bladder infection

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Asymptomatic Bacteriuria, Diabetes Mellitus, Pregnancy, Urinary Tract Infection

Outcome measures

Primary outcome

Prevalence of ASB, incidence of UTIs during pregnancy, diagnosed by dipstick and urine culture.

Secondary outcome

Hospitalization rate

Pregnancy duration

Birth weight

Prevalence causative uropathogens

Prevalence virulencefactors of E.Coli.

Study description

Background summary

Women with diabetes mellitus (DM) have a high incidence and complication rate of urinary tract infections (UTIs). UTIs are common during pregnancy, as well as asymptomatic bacteriuria (ASB). ASB may lead to UTI, pyelonephritis and sepsis in the mother and contribute to low birthweight babies and preterm birth (before 37 weeks). Pregnant women with DM or gestational diabetes (GDM) have two additive risk factors for developing a UTI with the possible consequences during and after pregnancy. Furthermore, in contrast to current Dutch guidelines, international guidelines include routine screening and treating ASB in pregnancy to prevent UTI and pyelonephritis. However the routine care abroad is not really comparable to obstetrical care in the Netherlands. Therefore,

more research in the Netherlands is indicated.

Study objective

What is the prevalence of ASB and incidence of UTIs during pregnancy in women with DM or GDM compared to pregnant women without diabetes? In addition, risk factors for ASB and UTIs, as well as consequences of ASB and UTIs will be investigated. These investigations include genotyping of different virulence factors of the causative bacteria.

Study design

Prospective cohort study

Study burden and risks

The burden of this research consists of data collection from the medical chart from the mother and the child, a short questionnaire on factors related to bacteriuria filled out by the pregnant woman at the routine screening and urine samples at the 12 (± 2 weeks) and 32 (± 2 weeks) weeks prenatal visit. Urine will be screened anonymous after these visits in the laboratory by a combination of a nitrite and leukocytes test. If one of these tests is positive a urine culture will be performed. The results of the tests stay anonymous and are not notified to the patient or to the treating doctor.

Contacts

Public

Universitair Medisch Centrum Groningen

Hanzeplein 1, entry 24
9713 GZ Groningen
Nederland

Scientific

Universitair Medisch Centrum Groningen

Hanzeplein 1, entry 24
9713 GZ Groningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

o Women

o Pregnant

o Older than 18 years old

o Informed consent

Exclusion criteria

o No understanding of Dutch or English language (we estimate that less than 5% of the patients have no understanding of Dutch language)

o Patients with pre-existing medical conditions with known association with UTI except for pregnancy and diabetes and without functional and anatomical abnormalities of the urinary tract

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	01-06-2009
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL25199.042.08