The most reliable way to collect urine in pregnant women to assess bacteriuria; comparison of three different methods

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What is the most reliable way, defined as the lowest percentage rate of urines which are contaminated, to collect urine in pregnant women to asses bacteriuria? Comparison of three different methods of collection: midstream morning urine, midstream...

Ethical review Approved WMO

Status Pending

Health condition type Maternal complications of pregnancy

Study type Observational non invasive

Summary

ID

NL-OMON34675

Source

ToetsingOnline

Brief title

The most reliable way to Collect Urine in Pregnant women (CUP-study)

Condition

- Maternal complications of pregnancy
- Bladder and bladder neck disorders (excl calculi)

Synonym

ASB, Asymptomatic bacteriuria, Bladder infection

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

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Intervention

Keyword: Asymptomatic bacteriuria, Pregnancy, Urinary tract infection

Outcome measures

Primary outcome

Urine contamination rate

Secondary outcome

Assocation between the results of the dipsticks, gram strains and cultures in

these patients

Study description

Background summary

To make a valid diagnosis of asymptomatic bacteriuria (ASB) or urinary tract infections (UTI), urine must be collected accurately. It is not known whether the method of urine collection influences the amount of contamination in pregnant women. However, it is important to investigate this, since pregnant women have weight gain, more vaginal discharge and a changed urinary tract anatomy compared to non pregnant women.

Study objective

What is the most reliable way, defined as the lowest percentage rate of urines which are contaminated, to collect urine in pregnant women to asses bacteriuria? Comparison of three different methods of collection: midstream morning urine, midstream urine without instructions and midstream clean catch urine.

Study design

Cross sectional study

Study burden and risks

The burden of this research consists of three urine samples during one prenatal visit in the second or third pregnancy trimester, > 22 weeks of pregnancy. The

urine will be screened anonymous after these visits in the laboratory by a combination of a nitrite and leukocytes test, a gram-stain and a urine culture.

Contacts

Public

Academisch Medisch Centrum

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

Women Pregnancy duration of at least 22 weeks Older than 18 years old Informed consent

Exclusion criteria

No understanding of Dutch or English language

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-02-2010

Enrollment: 100

Type: Anticipated

Ethics review

Approved WMO

Application type: First submission

Review commission: METC Amsterdam UMC

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 NL31247.018.10