# 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...

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| **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

## 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

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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

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|---|---|
| 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 |