Urinary tract infections in postmenopausal women revisited

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON53185

Source
ToetsingOnline

Brief title
UTIr

Condition

- Bacterial infectious disorders
- Urinary tract signs and symptoms

Synonym
bladder infection, Cystitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: NWO

Intervention

Keyword: observational cohort study, postmenopausal women, recurrent urinary tract infection, urinary tract infection

Outcome measures

Primary outcome

Urobiome composition by 16S rRNA sequencing/qPCR: alpha and beta diversities, relative and absolute abundances of key taxa (typically up to genus level), and urobiome clusters (urotypes).

Secondary outcome

• Urobiome composition by metagenomic sequencing: same as above but at species and strains level; plus relative abundances of bacterial (other than bacterial 16S genes) and non-bacterial genes in urine.

• Vaginal, vulvoperineal, and intestinal microbiome composition - same endpoints as described above for urobiome composition.

• Urine metabolome composition.

• Results of the co-culture and urothelium organoid experiments with bacterial isolates obtained from samples collected in the cohort study.

Study description

Background summary

Recurrent urinary tract infections (RUTI) are very common in postmenopausal women. The biological evidence-base required to improve diagnostic methods, prevention interventions, and clinical management needs strengthening.

Study objective

The primary objective is to explore the urine microbiome (urobiome) composition

of postmenopausal women with and without RUTI at five scheduled time points during one year of follow-up, as well as before, during, and after UTI episodes when they occur. Secondary objectives are to compare urobiome to vaginal, vulvoperineal, and intestinal microbiome compositions in the same women at the same sampling time points; to explore the metagenome and metabolome in a subset of women/samples; to make the cohort samples and data available for related mechanistic research; and to translate the findings to improved clinical diagnostics for the (early) detection of UTIs. The overall goal is to improve the treatment and prevention of UTIs in postmenopausal women with a RUTI diagnosis.

Study design

Observational prospective cohort study.

Study burden and risks

The study participants will not benefit directly from study participation other than receiving a reimbursement for their travel and time. The risks are judged as negligible because the study does not include any interventions. The logistics burden is judged as potentially high, depending on a participant*s personal circumstances and the number of UTIs during follow-up: all participants will be asked to visit the UMCU, host home visits, and/or self-sample at 5 scheduled time points during the year, and women who experience UTIs will be asked to host two additional home visits, and several additional days of self-sampling, per UTI episode. To minimise risks and burdens, women will be trained and supported by study staff, and some flexibility with study procedures will be allowed to ensure that burdens remain within each woman*s personal limits.

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

1. Postmenopausal woman, defined as having had the last menstrual period at least 12 months ago.
2. RUTI group: having had a UTI at least three times in the last 12 months OR Control group: not having had a UTI in the last 12 months and never having had a RUTI diagnosis in the past.
3. Willing and able to complete the expected tasks described in the study protocol, including answering questions in Dutch or English; allowing home visits by study staff as needed; allowing study staff to obtain medical information relevant to the study objectives from the GP; and allowing study staff to share pseudonymised study samples and data (i.e. identified by participant identification code only) within the UTIr project consortium.

Exclusion criteria

1. Having an anatomical abnormality or chronic disease of the urinary tract or kidneys, or having received a kidney transplant.
2. Having a urinary catheter in place.
3. Using exogenous progestogens and/or oestrogens and/or anti-oestrogen treatment. Women become eligible again if their last hormonal use is at least 6 months ago.
4. Having a chronic condition and/or using medications that significantly influence the immune system and/or bacterial growth. Women become eligible again if their last medication use is at least 6 months ago. Women who use supplements to prevent or treat UTIs (such as cranberries or d-mannose) are eligible. Women cannot use vaginal probiotics containing lactobacilli during the study; they can be enrolled after at least one month has passed since their last use.

5. Having to undergo a substantial planned medical intervention, such as surgery, during the follow-up period.
6. Planning a prolonged absence from the Netherlands during the follow-up period.
7. Women in both groups who have a genital infection at the time of recruitment must first be treated for that infection and can be included when at least 2 weeks have passed after the end of treatment and they are symptom-free.
8. Women in the RUTI group who have a UTI at the time of recruitment can be included but baseline procedures will be slightly adjusted.
9. Women in the RUTI group who use antibiotics chronically to manage their RUTI, or vaginal oestrogen-containing creams for RUTI prophylaxis, will be excluded in the first instance but may become eligible later on during recruitment if required to reach recruitment targets.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-05-2024
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	20-11-2023
Application type:	First submission

Review commission:	METC NedMec
Approved WMO Date:	05-12-2024
Application type:	Amendment
Review commission:	METC NedMec

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	NL84448.041.23