Mass spectrometry identification of true urinary tract infection in elderly women: the SENIOR pilot

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28149

Source
NTR

Brief title
SENIOR

Health condition

Urinary tract infection, asymptomatic bacteriuria

Sponsors and support

Primary sponsor: The Sponsor of the study is the LUMC. The study is funded by a ZonMw grant
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Biomarker levels (sensitivity, specificity, negative and positive predictive value) in women with and without UTI (including ASB)

Secondary outcome

Biomarker levels in women with upper versus lower UTI

Study description

Background summary

In community-dwelling elderly, the incidence of urinary tract infection (UTI) is higher for women than men, and increases significantly with age. Moreover, UTI is the most common infection in Dutch long-term care facilities (LTCF). Due to the high prevalence of asymptomatic bacteriuria (ASB) in elderly women (25-50%), the positive predictive value of pyuria and a positive urine culture is very low. Therefore, current guidelines require the presence of UTI-specific symptoms for antibiotic treatment. However, communication of symptoms may be difficult for elderly patients with cognitive impairment, and many elderly women have preexisting genitourinary symptoms, such as incontinence. A third of LTCF-patients with ASB are treated with antibiotics, contrary to guideline recommendations. Treatment of ASB has no effect on mortality or hospital admissions for UTI, but contributes to antibiotic resistance, drug toxicity and interaction, and carries an eight-fold increased risk of Clostridioides infection.
The primary objective of this proof-of-concept, pilot study is to identify specific urine biomarkers that can discriminate ASB from UTI in women over the age of 65. Our secondary objective is to evaluate whether urine biomarkers can discriminate upper from lower UTI. Seven different urine biomarkers will be quantified using mass spectrometry and ELISA. Patients will be recruited in long term care facilities, general practices and regional hospitals.

Study objective

We postulate that a specific urine biomarker or biomarker panel can discriminate ASB from UTI

Study design

There will only be one time point for patients with upper/lower UTI and patients without UTI. Patients with ASB will be asked to produce a second urine sample four weeks after the first culture, as ASB cannot be determined with one urine culture.

Intervention

No intervention, only collection of a urine sample

Contacts

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Eligibility criteria

Inclusion criteria

- Female, aged > 65
- Pyuria
- New onset of ≥ 2 symptoms: frequency, urgency, dysuria, suprapubic tenderness

Exclusion criteria

- Inability to express symptoms
- Immunosuppressive therapy
- Previous urological surgery
- Active glomerulonephritis
- Urologic malignancy
- Bladder irrigations
- Pretreatment with antibiotics in previous 48 hours
- UTI in preceding month
- Present urolithiasis
- Presence of urinary catheter

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-05-2021
Enrollment:	124
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-05-2021
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	NL9477
Other	METC-LDD : N21.020

Study results