

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

Gepubliceerd: 12-05-2021 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28149

Bron

NTR

Verkorte titel

SENIOR

Aandoening

Urinary tract infection, asymptomatic bacteriuria

Ondersteuning

Primaire sponsor: The Sponsor of the study is the LUMC. The study is funded by a ZonMw grant

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

No intervention, only collection of a urine sample

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	30-05-2021
Aantal proefpersonen:	124
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	12-05-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9477
Ander register	METC-LDD : N21.020

Resultaten