De-implementation strategy to reduce overtreatment of asymptomatic bacteriuria: the ROAB-study

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Our study aims to reduce inappropriate screening and treatment of ASB in emergency departments by 50%, improve healthcare quality, lower the increase in antimicrobial resistance, and save costs.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25918

Bron
NTR

Verkorte titel
ROAB

Aandoening

Asymptomatic bacteriuria is the presence of bacteria in the urine of a patient, who does not have symptoms of urinary tract infection (UTI). This is a common finding especially among women, elderly persons, and patients with urinary catheters. Guidelines strongly recommend not to screen for or treat asymptomatic bacteriuria with antimicrobials, except for specific patients at risk of developing a complicated UTI.

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC
Overige ondersteuning: the Netherlands Organisation for Health Research and Development (ZonMW)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The percentage of patients with ASB without risk factors or other alternative site of infections who are treated with antimicrobials.

Toelichting onderzoek

Achtergrond van het onderzoek

Antimicrobials for asymptomatic bacteriuria (ASB) is one of the most common unnecessary treatments. Earlier studies showed that this inappropriate treatment has a prevalence of 45%. With regard to international guidelines and antimicrobial stewardship, successful multifaceted interventions showed a decrease in overtreatment of ASB. The main objective is to reach a 50% reduction in overtreatment of ASB by using a de-implementation strategy. We will use a stepped wedge cluster randomized design for our multifaceted de-implementation strategy, comparing outcomes before and after introduction of our intervention in the emergency department of five hospitals (clusters) in the Netherlands. The de-implementation strategy consists of a combination of interventions, such as education, audit and feedback. All patients (≥18 years old) who had a urine test while presented at the emergency department will be screened for eligibility. The primary endpoint is overtreatment of ASB without risk factors (e.g. pregnancy, planned invasive urologic procedures and neutropenia). Secondary endpoints are the duration of antimicrobial treatment for ASB, the number of urine cultures and urinalysis per 1000 patients, and overtreatment of positive urinalysis in asymptomatic patients.
Ethical approval was obtained from Medical Ethics Research Committee of the Academic Medical Centre (Amsterdam, the Netherlands), with a waiver for informed consent. Local feasibility was obtained by the local institutional review boards of all participating hospitals. Our study aims to reduce inappropriate screening and treatment of ASB in emergency departments, improve healthcare quality, lower the increase in antimicrobial resistance, and save costs. If proven (cost)-effective, this study provides a well suited strategy for a nationwide approach to reduce overtreatment of ASB.

Doel van het onderzoek

Our study aims to reduce inappropriate screening and treatment of ASB in emergency departments by 50%, improve healthcare quality, lower the increase in antimicrobial resistance, and save costs.

Onderzoeksopzet

We will start the intervention periods every one or two months, depending on how many patients will be included during the first month.

Onderzoeksproduct en/of interventie

A multifaceted de-implementation strategy.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Our target size is at least 420 patients.
Patients ≥18 years old who had urine tests (culture and/or urinalysis), that were obtained during presentation at the emergency department will be screened for eligibility.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Negative urinalysis and negative urine cultures
- Patients with symptomatic UTI

- Patients with an alternate site of infection for which they receive antimicrobial treatment
- Patients with ASB and risk factors, defined as pregnant women, patients prior to planned invasive urologic procedures associated with mucosal trauma (including transurethral surgery of the prostate or bladder, ureteroscopy including lithotripsy, and percutaneous stone surgery), and high-risk neutropenia (defined as absolute neutrophil count <500 cells/µl).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2020
Aantal proefpersonen:	420
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Data collected from this study, including de-identified individual participant data, will be made available upon publication to investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. Proposals should be directed to the chief investigator Prof. Suzanne E. Geerlins (s.e.geerlings@amsterdamumc.nl); to gain access, data requestors will need to sign a data access agreement. The study protocol will be available as open-access publication.

Ethische beoordeling

Positief advies

Datum:	17-12-2019
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	NL8242
Ander register	METC AMC : W19_472

Resultaten