Point-of-care testen van CRP en procalcitonine bij urineweginfecties in verpleeghuizen

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Point-of-Care (POC) diagnostic tests will support clinical rules for diagnosing Urinary Tract Infections (UTIs)

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

Samenvatting

ID

NL-OMON27528

Bron
Nationaal Trial Register

Verkorte titel
PROGRESS

Aandoening

Urinary tract infection
Urineweginfectie

Ondersteuning

Primaire sponsor: Academical Medical Center
Overige ondersteuning: ZonMW 50-54100-98-114

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Sensitivity of the point-of-care (POC) test to identify patients with true UTIs, as derived from Receiving Operating Curves (ROC).

As there is no uniform definition of an UTI, a ‘true UTI’ is defined post-hoc using stringent criteria, including microbiology results and clinical response to adequate antibiotic therapy.
The following definition is defined:
1.Presence of at least 2 urinary (dysuria, urgency or frequency, new or worsened incontinence, suprapubic or costovertabral angle tenderness) OR non-specific (fever, confusion, delirium, anorexia, malaise) symptoms; AND
2.Positive urine leucocyte esterase tests AND
3.The presence of a uropathogen in urine at >10E4 CFU/mL (maximum of 2 uropathogens) AND
4.Symptom resolution in the course of adequate antibiotic treatment, where adequate treatment is defined by proven susceptibility of isolated uropathogens to the administered antibiotic.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Nursing homes are increasingly regarded as an important reservoir for the emergence of antimicrobial resistance (AMR). Suspected urinary tract infections (UTI) rank among the most common reasons for antibiotic use in nursing homes. However diagnosing UTI in this setting is challenging because of frequent non-specific symptomatology combined with high prevalence of asymptomatic bacteriuria (ASB), which complicates attribution of causality detection of bacteria in urine. The difficulty of distinguishing true UTI from bacterial colonization of the urinary tract results in frequent inappropriate antibiotic use. In in this study, PROGRESS aims to evaluate the use of blood C-reactive protein (CRP) and procalcitonin (PCT) measurements to distinguish between bacteriuria and true infection in elderly nursing home residents with suspected UTI.

The PROGRESS study aims to evaluate the use of blood C-reactive protein (CRP) and procalcitonin (PCT) measurements to distinguish between bacteriuria and true infection in elderly nursing home residents with suspected UTI. A good marker for diagnosing a true UTI will help reducing antimicrobial resistance (AMR) in nursing homes by better informed decisions about who to treat.

Antimicrobial resistance (AMR) rates vary substantially between nursing homes. In this study the antimicrobial susceptibility data will be analysed to assess the usefulness of Lot Quality Assurance Sampling-based (LQAS) surveillance to generate relevant local ABR data to guide local empirical treatment. If successful, these combined approaches will reduce ABR in nursing homes by better informed decisions about who to treat and how.

Objective:

I.To assess the utility of point-of-care measurements of blood CRP and PCT levels to support clinical rules for diagnosing urinary tract infections UTI in nursing home residents.

II. To assess the usefulness of LQAS–based surveillance in providing relevant AMR prevalence data to guide local empirical treatment choices in nursing homes.

III. To develop and assess strategies that facilitate implementation of point-of-care testing in nursing homes.

Study design:

18-month matched diagnostic accuracy study in several nursing homes of the University Network for Organisations of Elderly care of the VU University Medical Center (UNO-VUmc). The matching refers to the assessment of blood CRP and PCT levels simultaneously in the same study participants.

Study population:

Nursing home residents with suspected UTI based on current clinical rules.

Main study parameters/endpoints:

For part I: Sensitivity of the POC tests to identify patients with true UTIs

For part II: an LQAS-classification into high versus low AMR prevalence using pre-defined thresholds. Different thresholds for high and low prevalence will be tested

For part III Barriers and facilitators for the adoption and implementation of the POC-test in nursing homes

Doel van het onderzoek

Point-of-Care (POC) diagnostic tests will support clinical rules for diagnosing Urinary Tract Infections (UTIs)

Onderzoeksopzet

10 days

Onderzoeksproduct en/of interventie

C-Reactive Protein (CRP) and Procalcitonin (PCT) POC testing in nursing home residents clinically suspected of UTI.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Nursing homes residents clinically suspected of a urinary tract infection at the discretion of the attending physician

- Provided pre-emptive informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Suspected respiratory tract infection OR suspected other infection requiring antibiotic therapy
- Previous inclusion in the past 30 days

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	11-09-2017
Aantal proefpersonen:	440
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
- Dataset and codebook published together with metadata
- Without restrictions on use of dataset and codebook (licence CC0)
- DOI will be available when pubished on Figshare at submission main manuscript:

Ethische beoordeling

Positief advies

Datum:	25-05-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48851
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6293
NTR-old	NTR6467
CCMO	NL62067.029.17
OMON	NL-OMON48851

Resultaten

Samenvatting resultaten
Kuil SD, Hidad S, Fischer JC, et al. Sensitivity of point-of-care testing C-reactive protein and procalcitonin to diagnose urinary tract infections in Dutch nursing homes: PROGRESS study protocol. BMJ Open 2019;9:e031269. doi:10.1136/bmjopen-2019-031269.