PROGRESS: Point-of-care diagnostics to guide appropriate antimicrobial therapy of urinary tract infections in nursing homes

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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 develop and assess strategies that facilitate implementation of...

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

Summary

ID

NL-OMON48851

Source
ToetsingOnline

Brief title
Point-of-care diagnostics for UTI in nursing homes

Condition

- Bacterial infectious disorders

Synonym
Urinary tract infection; cystitis; urethritis; pyelonephritis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Nursing homes, Point-of-care, Urinary tract infection

Outcome measures

Primary outcome

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

For part II Barriers and facilitators for the adoption and implementation of

the POC-test in nursing homes

Secondary outcome

N/a

Study description

Background summary

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.

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

Study design

2 year 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 burden and risks

Group relatedness
The nature of the setting is one of the main reasons for this study, since diagnosing UTI in elderly nursing home residents is challenging because of frequent non-specific symptomatology. Part of the patients will be incapacitated, one of the reasons diagnosing UTI is complicated in this population. Moreover, inflammatory markers such as CRP or PCT behave differently with ageing and frailty, which emphasizes the need for research in this specific population.

Burden and risks
For this study a blood and urine sample are needed and medical information from the patient record will be extracted. Blood sample collection will be carried out by a trained doctor or (study) nurse. Collection of a single urine sample and single blood sample are both considered minimal invasive research procedures and are often performed as part of routine care. Therefore we argue that risk for both procedures is minimal. To further minimize the burden for the participants, we will make use of the participants daily routine for blood and urine sample collection. Collection methods will be determined with the participants and caretakers, depending on personal factors such as urine incontinence.
In the case of a legally incapacitated patient, any form of objection against participation, will result in ending the testing procedure. Patients will be diagnosed and treated following local guidelines.

Benefit
The patients will not directly benefit from this study because both the results of the blood sample (used for CRP and procalcitonin) and the urine sample (used for nitrite and leukocytes dipstick and urine culture) will not be reported to the patient or treating physician. Because the aim of this study is to assess the utility of CRP and PCT as POC-tests, we cannot report the results in this

part of the PROGRESS study. Patient will receive care as usual.

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

Nursing home residents clinically suspected of a urinary tract infection

Exclusion criteria

Suspected respiratory tract infection OR suspected other infection requiring antibiotic therapy

Previous inclusion in the past 30 days.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2017
Enrollment:	440
Type:	Actual

Ethics review

Approved WMO Date:	01-09-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-04-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-06-2019
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27528
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL62067.029.17
OMON	NL-OMON27528