Surveillance studie naar het voorkomen antibioticaresistentie bij uropathogenen in het verpleeghuis

No registrations found.

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

Summary

ID

NL-OMON26041

Source
Nationaal Trial Register

Brief title
PROGRESSplus

Health condition

Urinary tract infection
Urineweginfectie

Sponsors and support

Primary sponsor: Academical Medical Center (AUMC)
Source(s) of monetary or material Support: ZonMW 50-54100-98-114

Intervention

Outcome measures

Primary outcome

To use LQAS-based surveillance for providing AMR prevalence for selected antimicrobials in patients with suspected UTI

Secondary outcome

To identify barriers and facilitators for implementation of LQAS based surveillance in nursing homes and the use of LQAS-based surveillance data to inform local empirical antimicrobial treatment.

To describe differences in frequencies of bacterial contamination, bacterial overgrowth and UTIs between spontaneously voided urine samples and urine collected from diapers/incontinence pads in elderly with suspected UTI, suffering from urine incontinence

To assess the role of general signs and symptoms as predictors for UTIs in elderly nursing home residents

To understand the emergence and spread of AMR within nursing homes by molecular epidemiological analyses using whole genome sequencing of bacterial isolates from urine

Study description

Background summary

Urinary tract infections (UTIs) are one of the most common infections in nursing home residents. In Dutch nursing homes, an average weekly incidence of 10.3 per 1000 elderly residents was found (95% CI 9.8 – 10.8). Nevertheless there is a lot of uncertainty in recognition, diagnosing and treating UTIs. The following gaps in knowledge, also indicated in the recently published Dutch guideline on UTI in elderly, are focus of this study: (1) adequate treatment of UTI based on antimicrobial resistance (2) adequate urine sampling in case of urinary incontinence and (3)the role of non-specific symptomatology in UTIs

1) Antimicrobial resistance surveillance
Recent surveys in Dutch nursing homes showed high AMR rates against commonly used antibiotics for UTIs. For this reason, the Dutch Minister of Health emphasized the need for improved insights into the causes and consequences of AMR in nursing homes.
In addition, substantial differences in AMR prevalence between single homes in the same region are observed, ranging from less than 5% to more than 30% for ciprofloxacin resistance and ESBL production in Escherichia coli (E. coli). Rising resistance percentages lead to limited empirical treatment options. For the above reasons, local surveillance data at the level of individual nursing homes to guide empirical treatment are highly desirable. However, generation of such locally relevant data in a timely fashion is impractical using conventional population-based surveillance approaches as, for example, one would need around 600 isolates to determine a precise AMR prevalence of 10%. Therefore, innovative approaches involving efficient sampling strategies are needed. One such sampling strategy is Lot Quality Assurance Sampling (LQAS) which originates from industry: rather than estimating a precise prevalence, LQAS-based surveillance classifies a population (‘lot’, for example residents of a specific nursing home) as having either high or low AMR prevalence, predefined by

appropriate thresholds. Such classification is compatible with clinical practice since empirical treatment choices are typically based on threshold prevalences of AMR, e.g. guidelines recommend empirical use of cotrimoxazole when local AMR prevalence is below 20%.
An LQAS-based approach to reliably classify prevalence as high (above 10%) will only require less than 100 isolates, given certain pre-defined statistical parameters, instead of more than 500 isolates when using the conventional approach. These small sample sizes mean that timely generation of locally relevant AMR data becomes feasible. We have evaluated an LQAS-based AMR surveillance approach in Indonesian healthcare settings and have shown this to be reliable and feasible. Our analyses of existing AMR datasets from Dutch nursing homes have also shown the promising usefulness of LQAS as a classification tool, but no prospective studies in this setting have been performed.
Given the social mixing and frequent contact with healthcareworkers in nursing home settings the risk of AMR transmission is increased. Identified uropathogens will be used for bacterial typing to determine transmission.

2) Urine collection challenges
Proper urine cultures are essential to identify the causing micro-organism and guide antimicrobial therapy. Especially in increasing frequency of infections with resistant micro-organisms, susceptibility testing is needed. In guidelines clean-catch urine sample collection is recommended. However, the majority of nursing home residents suffer from cognitive impairment and urine incontinence, making this collection method challenging. In nursing homes disposable diapers/incontinence pads with super absorbing pads from different brands are widely used in patients with urine incontinence. Previous studies in a routine setting also suggest diapers can be used to collect urine for UTI diagnosis but studies in nursing home residents were small and inconclusive. We have shown in our previous laboratory study that presence of UTI (based on leucocyte detection by dipstick and growth of uropathogens at ≥ 104 CFU/mL) is not-inferior in diaper samples compared to reference urine samples . Since this was a laboratory study, uncertainty remains whether diaper collected urine samples can be used for UTI diagnosis. One of the fears of using diapers in clinical practice is bacterial overgrowth or contamination resulting in increased number of UTI diagnosis or even hampering bacterial culture interpretation.

In this study we aim to explore if urine collected by diapers (after wearing) results in bacterial overgrowth or bacterial contamination, thus hampering UTI diagnosis or even leads to increased number of UTI diagnosis.

3) Recognition of UTI role of non-specific symptoms
Recognition of UTIs in nursing home residents is challenging, due to frequent non-specific symptomatology which hampers distinction between asymptomatic bacteriuria and true UTI’s. The majority of nursing homes in the Netherlands consist of psychogeriatric wards (57%), for elderly residents suffering from cognitive impairments, mainly Alzheimer disease. Their ability to verbally communicate or express classical symptoms of UTI, such as dysuria, urgency or frequency, is often limited. The most frequently presented symptom in elderly residents leading to antibiotic prescription for a suspected UTI is an altered mental status (43.3%), while classical symptoms as dysuria, urgency and frequency are present in the minority of cases (0 – 3.8%). Confusion or an altered mental state are nonspecific symptoms and can result from other infectious and non-infectious diseases in the elderly residents. In

the recently published Dutch guideline on Urinary tract infections in frail elderly, non-specific symptoms are not considered as signs of UTI, but evidence is lacking. So it remains unknown whether non-specific symptoms can support UTI diagnosis in nursing home residents.

Study embedding
This study builds on a previous study (PROGRESS) and will use the nursing home infrastructure, data collection methods and study set-up developed for the initial PROGRESS study. The primary objective of the initial PROGRESS study was to evaluate the diagnostic accuracy of blood levels of C-reactive protein and procalcitonin, measured by Point-of-Care tests (POCT), for diagnosis of urinary tract infections in nursing home residents. However, this study was recently discontinued prematurely, based on an interim-analysis showing that neither of the POCT was anticipated to reach a pre-specified minimum sensitivity of 65%, hence continuing this study for the primary study outcome was considered futile. However, evaluation of LQAS-based surveillance represented a secondary objective of this project, which was not addressed yet. This objective will be addressed in the current 'PROGRESS plus' study, along with a number of other objectives.

Previously collected data in "PROGRESS" (± 300 participants) will be used in "PROGRESS plus" as informed consent for (re)use of data for original and additional research objectives is obtained during the first study. Data collection in "PROGRESS plus" will be identical. As no blood specimens will be required for the current study (in contrast to the original PROGRESS study), specimen collections will be restricted to urine and (when available) urinary incontinence pads (see secondary obj. 1). In- and exclusion criteria will be identical.

See NL6293 / NTR6467 for PROGRESS study

Study objective

LQAS will support more adequate antibiotic prescription for Urinary Tract Infections (UTIs) per nursing home (group) based on local antibotic resistance patterns
The PROGRESSplus study also provides insight in recognition of UTIs, to improve UTI management in future

Study design

10 days

Contacts

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Eligibility criteria

Inclusion criteria

Elderly nursing home residents and elderly residents of rehabilitation wards (≥ 65 year) with suspected urinary tract infection based on the attending physician’s medical judgement
No objection on participation by representative or nursing home resident

Exclusion criteria

Previous inclusion in the past 30 days
Suspected respiratory tract infection
Suspected other infection in need of antibiotic treatment

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-02-2020
Enrollment:	600

Type: Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
- 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:

Ethics review

Positive opinion
Date: 08-06-2020

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	NL8697
Other	Dagelijks Bestuur van de METc VUmc : N/A

Study results

Summary results
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.