Bedside testing for lower respiratory tract infections in nursing homes.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23398

Source
Nationaal Trial Register

Brief title
UPCARE

Health condition

Lower respiratory tract infection;
Pneumonia;

Lage luchtweginfectie;
Pneumonie;
Longontsteking

Sponsors and support

Primary sponsor: VU University medical center
Source(s) of monetary or material Support: ZonMw
Saltro/Orion Diagnostica

Intervention

Outcome measures

Primary outcome

The central research question is whether the use of CRP POCT results in a reduction in antibiotic prescribing for NH residents with suspected LRTl, without any negative consequences for patient recovery

The primary outcome is antibiotic prescribing for suspected LRTl at index consultation (yes/no).

Secondary outcome

Secondary research questions:

1) Associations between CRP POCT values and:

a. signs and symptoms in NH patients with suspected LRTI

b. antibiotic treatment (yes/no)

2) Cost-effectiveness and cost-benefit of the use of CRP POCT compared to usual care for NH patients with suspected LRTI.

Study description

Background summary

A cluster Randomized Controlled Trial (cRCT) will be conducted in NH organizations in the Netherlands, with the NH as the unit of randomization. NHs in the intervention group will use CRP POCT, and NHs in the control group will provide care as usual for NH residents with (suspected) LRTI.

Study objective

Antibiotics are over-prescribed for lower respiratory tract infection (LRTI) in nursing home (NH) residents due to diagnostic uncertainty. Inappropriate antibiotic use is undesirable both on patient level, considering their exposure to side-effects and drug interactions, and on societal level, given the potential development of antibiotic resistance. The diagnosis of LRTI is challenging in NHs, as NH residents often lack typical symptoms, and because cognitive disabilities can impede communication of experienced complaints. In addition, diagnostic tools are often not well-applicable or not directly available in the NH setting. C-reactive protein (CRP) point-of-care testing (POCT) may be a promising diagnostic tool to reduce unnecessary antibiotic use for LRTI in NHs.

The overarching aim of the UPCARE study is to achieve better antibiotic stewardship by introducing a cheap, quick and easy-to-use diagnostic tool for the evaluation of LRTI in NHs: CRP POCT.

Study design

During the study period (September 2018-April 2020), data collection occurs through an electronic patient file. For each diagnosis “suspected LRTI” entered by a physician in the electronic patient file, a screen will pop-up with questions about study eligibility and informed consent. In a subsequent screen the physician can fill out the research questionnaire. Follow-up information on patient recovery and changes in policy is asked one and three weeks later. In addition, pharmacy data will be collected on total antibiotic use in the NH during the study period.

Intervention

A cluster randomized controlled trial (cRCT) will be conducted in NH organizations. Participating NHs will be randomized to the intervention or control group. ln the control group, care as usual is provided. ln the intervention group, physicians provide care as usual including C-Reactive Protein (CRP) Point-Of-Care-Testing (POCT) for patients who are diagnosed with 'suspected LRTl'. Elderly care physicians consider CRP POCT results along with the clinical features of the patient in their decision to prescribe or not prescribe antibiotics.

Contacts

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Eligibility criteria

Inclusion criteria

- Residence at a nursing home;

- Residence at a psychogeriatric, somatic, or geriatric rehabilitation department

- A new diagnosis 'suspected lower respiratory tract infection'

Exclusion criteria

- The patient no longer wishes to be treated with antibiotics in case of a lower respiratory tract infection;

- Recent use of antibiotics (oral, intravenous, or intramuscular) in the week preceding the current respiratory tract infection;

- Recent infection, other than a respiratory tract infection, in the week preceding the current respiratory tract infection;

- The patient receives palliative or terminal care.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-09-2018
Enrollment:	671
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
The datasets generated and/or analysed during the current study will be deposited in the repository DANS(EASY) after publication of the research results, within a maximum of nine months post study termination. The dataset(s) involved will be anonymised/pseudonymised and can be accessed under restrictions.

Ethics review

Positive opinion Date:	29-08-2018
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	NL5054
NTR-old	NTR7452
Other	METc VUmc registratienummer : 2017.503

Study results