Using Point-of-care C-reactive protein to guide Antibiotic prescribing for Respiratory tract infections in Elderly nursing home residents

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CENTRAL OBJECTIVETo investigate whether the use of CRP POCT results in a reduction in antibiotic prescribing for NH residents with suspected LRTI, without any negative consequences for patient recovery.SECONDARY OBJECTIVES1) To explore potential...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON48719

Source
ToetsingOnline

Brief title
UPCARE

Condition

- Respiratory tract infections

Synonym
Lower respiratory tract infection; pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: ZonMw,Saltro diagnostisch laboratorium

Intervention

Keyword: Antibiotic prescribing, CRP point-of-care testing., Lower respiratory tract infections, Nursing homes

Outcome measures

Primary outcome

CENTRAL RESEARCH QUESTION:

Determinant: use of CRP POCT (yes/no)

Outcome: antibiotic prescribing for patients with suspected LRTI at index

consultation (yes/no)

SUB RESEARCH QUESTION 1A:

Determinant: signs and symptoms

Outcome: CRP-value

SUB RESEARCH QUESTION 1B:

Determinant: CRP-value

Outcome: antibiotic prescribing (yes/no)

SUB RESEARCH QUESTION 2:

Determinant: costs related to intervention (CRP POCT and regular health care

costs) versus control (regular health care costs)

Outcome: percentage of antibiotic prescribing, reduction in antibiotic

prescribing in euros.

SUB RESEARCH QUESTION 3: potential barriers and facilitators for the use and implementation of CRP POCT in NHs.

Secondary outcome

Secondary variables measured in the cRCT:

At index consultation:

o Patient characteristics (e.g. demographics)

o Symptoms (e.g. cough, fever, confusion)

o Additional diagnostics (e.g. culture, X-ray, CRP laboratory test (venipuncture blood))

o Information on antibiotic prescribing (type, dosage, duration)

At follow-up consultations:

o Patient recovery (yes/no; clinical signs and symptoms: increase/decrease/no change in type or severity of symptoms).

o Changes in treatment policy (e.g. additional diagnostics; changes in antibiotic prescribing (yes/no, type, dosage, duration)

o Hospital referral

o Complications

o Mortality

During total period of cRCT:

o Total number of antibiotic prescriptions per nursing home organization

Secondary variables in the cost-effectiveness study:

Costs related to the use of the CRP POCT, antibiotic prescriptions,

consultation of physicians in the nursing home, additional diagnostics,

hospital referral and other health care usage, and complications of treatment.

Study description

Background summary

Antibiotics are among the most commonly prescribed drugs in nursing homes (NHs), with 47% to 79% of the residents receiving at least one antibiotic course annually, while almost 25% of these prescriptions do not seem required at the index consultation. Inappropriate antibiotic use is undesirable both on the patient level (because of exposure to side-effects and drug interactions) and the societal level (because it contributes to the development of antibiotic resistance).

About one-third of the antibiotic prescriptions in Dutch NHs are for treatment of suspected lower respiratory tract infections (LRTl). Diagnosing LRTl is challenging in this setting as NH residents often lack typical symptoms, and cognitive disabilities can impede communication of experienced complaints. ln addition, X-ray, bacterial culture and laboratory research are often not well-applicable in the vulnerable NH population or not directly available in this setting. The resulting diagnostic uncertainty leads to AB prescribing to be 'better safe than sorry', an attitude towards antibiotic prescribing that can be further enforced by a variety of external factors, such as expectations of patients, family members and nursing staff. Together, these factors increase the chance of unnecessary antibiotic prescribing for NH residents.

ln general practice, diagnostic uncertainty and patient expectations play a role as well in treatment decisions regarding LRTl. ln this setting, it has been investigated whether the use of C-reactive protein (CRP) *point-of-care testing (POCT) can improve antibiotic prescribing for LRTl. With CRP POCT, capillary blood tests are performed with test results available within minutes: the resulting CRP values are an indicator of presence and severity of inflammation. Several studies demonstrated that adding CRP values to the evaluation of clinical signs and symptoms indeed improves the reliability of the diagnosis pneumonia. The use of CRP POCT in general practice showed a reduction in antibiotic use in patients with suspected LRTI. This appeared cost-effective in comparison with usual care. These findings were confirmed by other recent studies, which resulted in the incorporation of the CRP POCT in the guideline 'Acute cough' of the Dutch College of General Practitioners (NHG), and consequently in the large-scale implementation of CRP POCT in general practices in the Netherlands.

CRP POCT may be a promising tool to reduce unnecessary antibiotic use for LRTl in NHs as well, considering the large degree of diagnostic uncertainty and other factors that influence antibiotic prescribing for this population. Previous studies indeed showed that CRP is an useful indicator for the severity of LRTI in NHs, However, the effectiveness of CRP POCT on antibiotic prescribing has not been investigated in NHs. This is the main reason for the current limited use of the CRP POCT in NHs, despite its incorporation into the NHG guideline, which is also acted upon by physicians in NHs.

We hypothesize that the implementation of CRP POCT for suspected LRTl in NHs will lead to a clinically relevant reduction in antibiotic use of at least 15%, without any negative consequences for patient recovery.

Study objective

CENTRAL OBJECTIVE
To investigate 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.

SECONDARY OBJECTIVES
1) To explore potential associations between CRP POCT values and A) signs and symptoms in NH patients with suspected LRTl, B) antibiotic treatment.
2) To investigate cost-effectiveness and cost-benefit of the use of CRP POCT in the NH setting.
3) To investigate potential facilitators and barriers for the use and implementation of CRP POCT in the NH setting.

Study design

CENTRAL RESEARCH QUESTION
A cluster randomized controlled trial (cRCT) will be conducted in a 1.5-year period to answer the central research question. 10-12 nursing home (NH) organizations will be recruited to participate in the cRCT. Allocation of control and intervention groups will occur with randomization at NH organization (cluster) level.

Participating NH organizations will be randomized to an intervention or control group. In both groups, care as usual is provided, however, in different forms. ln the control group, suspected LRTI are evaluated based on clinical signs and symptoms, possibly supplemented with additional diagnostics such as a CRP laboratory test using blood collected by venipuncture, culture or X-ray (the latter two being only sporadically applied in nursing homes). ln the intervention group, physicians can use CRP POCT * a different, less commonly used form of usual care, in addition to their evaluation of clinical signs and symptoms and possibly other additional diagnostics. There are three repeated

measures where case report forms are completed en submitted by physicians within the electronic patient file: at the index consult (where LRTI is diagnosed, with or without the aid of CRP POCT), and two follow-up measurements at 1 and 3 weeks after the index consultation. In addition, pharmacy data for each NH will be collected retrospectively on total antibiotic use in the NH during the study period.

SUB RESEARCH QUESTION 1
Data of patients in the intervention group of the cRCT will be used to investigate possible associations between CRP POCT values and A) signs and symptoms in NH patients with suspected LRTl (i.e. do CRP POCT values correlate with certain signs and symptoms?), and B) antibiotic treatment (i.e. what are the ranges of CRP POCT values within which physicians decide to prescribe antibiotics?).

SUB RESEARCH QUESTION 2
An economic evaluation will be performed from a societal perspective, using cost-effectiveness and cost-benefit analyses.

SUB RESEARCH QUESTION 3
We will conduct a facilitator and barrier analysis on the use and implementation of CRP POCT in the NH setting. Semi-structured qualitative interviews and focus groups will be conducted with both NH professionals (e.g. physicians, nursing staff) and NH management. A topic list will be developed, with three dimensions of factors that influence the use of CRP POCT: on the cultural (e.g. financial mechanisms), contextual (e.g. organizational factors) and the behavioral (e.g. attitudes) level. Also included in the topic list are potential barriers and facilitators for the use of CRP POCT specifically for mentally incompetent nursing home residents.

Data collection will continue until data saturation has been achieved (i.e. no new barriers and facilitators are being identified), and to this end data analysis will coincide with data collection.

Intervention

ln the control group, care as usual is provided for patients with suspected LRTI: the evaluation of suspected LRTI is based on the examination of clinical signs and symptoms, possibly supplemented with additional diagnostics such as CRP laboratory testing using blood collected by venipuncture, culture or X-ray (the latter two only being sporadically applied in nursing homes). In the intervention group, physicians have access to CRP POCT, and evaluate suspected LRTI based on clinical signs and symptoms combined with CRP POCT results and possibly additional diagnostics. The CRP POCT is performed by measuring the concentration CRP in a finger prick blood, which indicates the presence and severity of inflammation.

The reference value of CRP is <10mg/L for healthy persons. Reference values in elderly people with comorbidity are marginally deviant from the reference value in healthy people, with on average only a couple unit increase in mg/L due to comorbid conditions. The CRP-value increases rapidly (within 6-8 hours) after inflammatory stimuli, and a peak level is reached after approximately 48 hours. The guideline "acuut hoesten" of the Dutch Society of General Practice* includes the following information on cut-off values of CRP in cases of suspected LRTI: a CRP-value of <20 mg/L indicates that pneumonia can be excluded with great certainty, and a CRP >100 mg/L strongly suggests pneumonia. In case of a CRP-value of 20-100 mg/L the presence of certain clinical signs and symptoms, and other risk factors, have more weight in the treatment decision-making.

Prior to the study onset, physicians from NH organizations in the intervention group will receive a training on the background and use of CRP POCT, and interpretation of CRP POCT results. Part of this training will involve information on ways to stimulate the blood circulation in the patient's fingers, as decreased blood circulation may hamper the procurement of a blood sample. The following methods to stimulate blood circulation, with due consideration to the patient's state of mobility, will be discussed: asking the patient to wave his/her arms, clap his/her hands, wash his/her hands in warm water, or hold a glove with warm water. If available at the site of the NH, an infrared lamp can be used to warm the patient's hand.

* With reference to information on CRP POCT in the guideline "acuut hoesten" of the Dutch Society of General Practice ("Nederlands Huisarts Genootschap"): https://www.nhg.org/standaarden/volledig/nhg-standaard-acuut-hoesten

Study burden and risks

Nursing home residents participating in this study will experience minimal burden. The number and timing of physician consultations are not impacted negatively by participation in the study. Also, patients are not involved in the data collection themselves (this occurs through the electronic patient file). In the intervention group, patients will undergo blood collection via finger prick once at the index consultation and if necessary at follow-up consultations. The burden the patient will experience from this finger prick is inconvenient at most, given that other types of diagnostics using finger prick blood collection are common practice in nursing homes (D-dimer, blood glucose) without any problems. The finger prick will be discontinued for patients who hitherto consented to participate, but at the consultation show signs of resistance towards the finger prick. The physician judges whether resistance (verbal and/or non-verbal behavior that is a more excessive manifestation of the usual reaction to situations deviant to daily routine) is the case in the instance, and consults with other caregivers if necessary. In case of resistance, the patient will receive usual care without the CRP POCT (using finger prick blood collection).

Participants do not have risk of (minor) harm/injury because of blood collection via finger prick. A possible scenario where the participant may have risk of an inappropriate treatment policy and consequently higher morbidity/mortality risk involves a prematurely timed CRP POCT. This situation would entail the CRP POCT being performed at a time where CRP values are still rising, resulting in non-prescribing or delayed prescription. However, this risk is minimal, which is also apparent from the application of CRP POCT in general practice, given that physicians do not solely rely on CRP-values in their decision on treatment policy but rather use CRP POCT as an additional tool in a spectrum of clinical findings. If patients show signs of severe illness, they are always followed-up by health care professionals/ the physicians, even in the case of low CRP-values at earliest consultations. Consequently, changes in clinical signs/symptoms can be adequately followed-up using additional diagnostics and/or changes in treatment policy. These scenarios will be given its due consideration in the training physicians from participating (intervention group) nursing homes will receive to adequately apply and interpret CRP POCT results.

If the hypothesis of the UPCARE study turns out to be correct, LRTI patients in the intervention group will receive improved care (adequate and timely treatment) because of improved diagnostics. Improved care entails less unnecessary antibiotic prescriptions and thus less side effects, medicine interactions, and antibiotic resistance. Also, if patients have different underlying diseases (other than LRTI/pneumonia, not requiring antibiotic treatment) they will receive treatment more appropriate to their signs and symptoms. Also, the CRP POCT can be considered a less invasive intervention compared to the CRP laboratory test, with respect to the type of blood collection (via finger prick respectively venipuncture). Study participation does not encompass specific advantages for patients in the control group.

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 with a new diagnosis *suspected lower respiratory tract infection*

Exclusion criteria

- The patient resides at a palliation/hospice care department of the nursing home
- The patient wishes not to be treated with antibiotics (anymore)
- The patient is already taking antibiotics
- The patient is (also) diagnosed with a different type of infection

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-09-2018
Enrollment:	671
Type:	Actual

Ethics review

Approved WMO Date:	28-03-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-07-2019
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

No registrations found.

In other registers

Register	ID
CCMO	NL62832.029.17