CRP-POCT in suspected airway infected patients in the long-term care facility

Published: 18-01-2017
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The main objective is to investigate the additional value of CRP-POCT (C-reactive protein point-of-care-test) testing in patients suspected of airway infections in long-term care facilities.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON43304

Source
ToetsingOnline

Brief title
CRP-SAIE (CRP-suspected airway infected elderly)

Condition

- Bacterial infectious disorders
- Respiratory tract infections

Synonym
pneumonia, respiratory tract infection

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Opella
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Aged, C-Reactive Protein, Point-of-Care Testing, Respiratory Tract Infections

Outcome measures

Primary outcome

Main study parameters/endpoints: The main endpoint is a difference in

first-consult-prescribed antibiotic use in patients who had a CRP test.

Secondary outcome

- relation between height of CRP and number of antibiotic prescriptions

- relation between parameters for illness and number of antibiotic prescriptions

- the value of pre-test illness according to the physician.

Study description

Background summary

Rationale: Patients in long-term care facilities often receive treatment for health-care associated infections based on history and physical examination. We aim to study the additional value of a CRP test on top of the *best common practice*.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Both patient groups receive best common practice. On top of that, the intervention group receives an extra test, which is a *finger-prick* to catch a small amount of blood, one drop. This test taking will hurt somewhat, but a regular venous blood taking has more disadvantages, i.e. chance of a hematoma, requires transportation to a laboratory. As patients stay inside their living, there is no hospital visit necessary and there are no questionnaires to fill in. We think this study is therapeutic, since in other populations (primary care) CRP POCT testing already is proved to be effective.

Study objective

The main objective is to investigate the additional value of CRP-POCT

(C-reactive protein point-of-care-test) testing in patients suspected of airway infections in long-term care facilities.

Study design

Location-randomised explorative pilot study.

Intervention

The intervention will consist of one blood test for the patiënt and a questionnaire for the physician.

Study burden and risks

Both patient groups receive best common practice. On top of that, the intervention group receives an extra test, which is a *finger-prick* to catch a small amount of blood, one drop. This test taking will hurt somewhat, but a regular venous blood taking has more disadvantages, i.e. chance of a hematoma, requires transportation to a laboratory. As patients stay inside their living room, there is no hospital visit necessary and there are no questionnaires to fill in for the subjects. We think this study is therapeutic, since in other populations (primary care) CRP POCT testing already is proved to be effective.

Contacts

Public
Stichting Opella

Barones van Lyndenlaan 1
Bennekom 6721PK
NL
Scientific
Stichting Opella

Barones van Lyndenlaan 1
Bennekom 6721PK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All institutionalized patiënts with suspected airway infection

Exclusion criteria

Patients, or their first legal representative, who do not sign the informed consent, will be excluded. Also, if the physician wants to give antibiotics nonetheless, patients will be excluded and if a patient doesn*t want to receive antibiotic treatment anymore, exclusion will follow as well. If a patiënt, representative or physician assesses the test as too painful or traumatic for the patient.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	15-02-2017
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	CRP POCT meter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-01-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-04-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-08-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL58820.091.16