C-reactive protein assisted prescribing for respiratory tract infections to stimulate Antibiotic stewardship; a randomised controlled trial in general practice

Published: 22-10-2007
Last updated: 09-05-2024

To determine the effect of point of care (PoC) C-reactive protein (CRP) testing and delayed prescribing on antibiotic prescribing for acute lower respiratory tract infections (LRTI) and acute rhinosinusitis in general practice.

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

Summary

ID

NL-OMON31304

Source
ToetsingOnline

Brief title
CAPRESA

Condition

- Respiratory tract infections

Synonym
respiratory tract infections

Research involving
Human

Sponsors and support

Primary sponsor: Orion Diagnostica Oy
Source(s) of monetary or material Support: Orion Diagnostica

Intervention

Keyword: antibiotics, C-reactive protein, primary care, respiratory tract infections

Outcome measures

Primary outcome

Prescribing rates at index consultation (day 0), defined as immediate, delayed or no antibiotics

Secondary outcome

- Total antibiotic exposure over a period of 28 days, defined as the number of patients receiving immediate antibiotics or filling a delayed prescription for antibiotics within 28 days of index consultation (day 0)
- Clinical recovery
- Patient satisfaction and enablement
- Reconsultation within 28 days
- Evaluation of GPs' estimation of CRP value based on usual diagnostic work-up (medical history and physical examination) compared to actual CRP test result.
- CRP value on day 0 and day 7 in relation to perceived degree of illness (VAS, Visual Analogue Scale).

Study description

Background summary

About 85-90% of all antimicrobials are prescribed in primary care and up to 80%

of these are for respiratory tract indications. Most of these antibiotic prescriptions are of questionable value. This unnecessary prescribing leads to antimicrobial resistance, described as one of the most serious public health issues of our time.

The usual diagnostic work-up (history and physical examination) by general practitioners (GPs) is not accurate to diagnose or rule out pneumonia in patients with acute cough. In a previous study we found that a C-reactive protein (CRP) test result of less than 20 reduced the absolute risk of a pneumonia to less than 2%. Since the test results are available in four minutes (using a finger prick blood sample), a low CRP test result at hand is useful in reassuring both the doctor and the patient that prescribing antibiotics are not indicated in most cases.

In recent years the additional value op CRP for LRTI and rhinosinusitis has been widely proven, but GPs in the Netherlands are still relatively unfamiliar with point of care (PoC) CRP testing. We are currently investigating the effect of PoC CRP testing, with or without communication skills training for GPs, on antibiotic prescribing rates for LRTI. The results will be available at the end of 2007. Delayed prescribing of antibiotics is another method that has proven to decrease prescribing rates for RTI in recent years. In this fashion the GP hands out the prescription, but the patient will only collect the antibiotic if symptoms do not resolve within a certain time.

These two promising strategies in combating unnecessary prescribing for self-limiting respiratory tract infections have not been combined in a trial so far. Moreover, since GPs may need assistance in building confidence, specific guidance on interpretation of the CRP test results and management may be helpful in (further) reducing unwarranted antibiotic prescriptions.

Study objective

To determine the effect of point of care (PoC) C-reactive protein (CRP) testing and delayed prescribing on antibiotic prescribing for acute lower respiratory tract infections (LRTI) and acute rhinosinusitis in general practice.

Study design

Randomised controlled trial in general practice

Intervention

PoC CRP assisted antibiotic prescribing including delayed prescribing compared to usual care

Study burden and risks

The subjects will not have any direct advantages, or disadvantages, by participating in the project. The management (including decisions about additional investigations and treatment) will be at the discretion of the GP. Patients will undergo two finger pricks (at day 0 and day 7 of the study). This procedure is comparable to the daily pricks in diabetic patients or the finger prick used to measure hemoglobin.

There are no recognized risks associated with the CRP test. No adverse events were recorded in a previous trial of our group of 431 patients, in which CRP PoC was performed at index consultation. Complications, side effects and adverse events therefore are highly unlikely. The same holds for the strategy of delayed antibiotic prescribing. The GP remains fully responsible for management and may change management at any time.

Contacts

Public
Orion Diagnostica Oy

P.O. Box 83
FI-02101 Espoo
Finland
Scientific
Orion Diagnostica Oy

P.O. Box 83
FI-02101 Espoo
Finland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

LRTI:
First consultation of current episode of acute cough (duration <4 weeks)
Regarded by the GP to be caused by an acute lower respiratory tract infection
- At least one out of following 4:
Shortness of breath / wheezing / chest pain / auscultation abnormalities
- At least one of the following 5:
Fever / perspiring / headache / myalgia / feeling generally unwell
Rhinosinusitis:
First consultation of current episode of rhinosinusitis (duration <4 weeks)
At time of consultation both of the following signs / symptoms:
1. purulent nasal discharge by self-report or by physical examination
2. unilateral or bilateral frontal or maxillary pain

Exclusion criteria

Patients who require immediate admission to hospital
Patients who have no understanding of written and/or Dutch language
Patients who previously participated in the study
Patients who currently use antibiotic or have taken an antibiotic in the past 2 weeks
Patients who have been hospitalized in the past 2 weeks
Severely immuno-compromised patients

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2007

Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	22-10-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL19561.060.07