

Improving Management of Patients with Acute Cough by C-reactive protein point of care testing and Communication Training

Submission date 04/08/2005	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 04/08/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/05/2013	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR51

Study information

Scientific Title

Point of care C-reactive protein test and enhanced communication skills for managing acute cough due to lower respiratory tract infection in general practice - cost-effectiveness and effect on diagnostic testing, antibiotic prescribing and recovery: a randomised controlled trial

Acronym

IMPAC3T

Study objectives

1. To what extent will the introduction of the C-reactive protein (CRP) point of care test and enhanced communication skills for managing lower respiratory tract infection (LRTI) in general practice, either separately or combined, lead to an enhancement of patient recovery, a reduction in other diagnostic testing, use of other medical services and a reduction in antibiotic prescribing?
2. To what extent are these reductions cost-effective?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local ethics committee

Study design

Randomised active-controlled factorial trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute cough, respiratory tract infection

Interventions

Randomisation at the level of practice. Factorial randomisation into four groups:

1. Access to and training in Point of Care (PoC) CRP plus communication training
2. Access to and training in PoC CRP alone
3. Communication training alone
4. Usual care

Point of Care CRP:

Access to and training in use of automatic CRP test device. Sample is one drop of whole blood from a finger prick.

Communication training:

Shared decision making using Simulated Patient in Clinical Encounter (SPICE) method.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Change (decrease) in antibiotic prescription
2. Clinical recovery and return to normal work and activities

Key secondary outcome(s)

1. Cost-effectiveness of PoC CRP and communication training
2. Use of medical services, including re-consultation
3. Change (decrease) in diagnostic testing other than PoC CRP

Completion date

01/08/2008

Eligibility**Key inclusion criteria**

1. First consultation of current episode of acute cough (duration less than four weeks)
2. Regarded by the General Practitioner (GP) to be caused by an acute lower respiratory tract infection
3. At least one out of following four:
 - 3.1. Shortness of breath
 - 3.2. Wheezing
 - 3.3. Chest pain
 - 3.4. Auscultation abnormalities
4. At least one of the following five:
 - 4.1. Fever
 - 4.2. Perspiring
 - 4.3. Headache
 - 4.4. Myalgia
 - 4.5. Feeling generally unwell

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients who require immediate admission to hospital
2. Patients who have no understanding of written and/or spoken Dutch language

3. Patients who previously participated in the study
4. Patients who currently use antibiotic or have taken an antibiotic in the past two weeks
5. Patients who have been hospitalised in the past six weeks

Date of first enrolment

01/11/2005

Date of final enrolment

01/08/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

P.O. Box 616

Maastricht

Netherlands

6200 MD

Sponsor information

Organisation

University Maastricht (Netherlands)

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/05/2009		Yes	No
Results article	results	01/03/2013		Yes	No
Protocol article	protocol	29/03/2007		Yes	No