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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	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/08/2005	**Overall study status** Completed	
Last Edited 30/05/2013	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof G J Dinant

Contact details
P.O. Box 616
Maastricht
Netherlands
6200 MD
+31 (0)43 388 2396
geertjan.dinant@hag.unimaas.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/11/2005

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

Age group

Adult

Sex
Both

Target number of participants
400

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)

Sponsor details
P.O. Box 616
Maastricht
Netherlands
6200 MD

Sponsor type
University/education

Website
http://www.unimaas.nl/default.asp?taal=en

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	29/03/2007		Yes	No
Results article	results	05/05/2009		Yes	No
Results article	results	01/03/2013		Yes	No