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

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
04/08/2005		[X] Protocol		
Registration date	Overall study status	[] Statistical analysis plan		
04/08/2005	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
30/05/2013	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

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