GRACE (Genomics to combat Resistance against Antibiotics for Community acquired LRTI in Europe) INTRO (INternet TRaining for antibiOtic use) Trial

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This study will compare antibiotic prescribing levels for practices trained via the GRACE INTRO programme (a self directed web based learning package combined with patient booklets), with those not trained, and in addition will determine whether the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON36801

Source
ToetsingOnline

Brief title
GRACE INTRO

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Respiratory tract infections

Synonym
cough, Lower Respiratory Tract Infections (LRTI)

Research involving
Human

Sponsors and support

Primary sponsor: University of Southampton, contact person Prof Paul Little
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Antibiotics, Lower Respiratory Tract Infections, Primary care, Resistance

Outcome measures

Primary outcome

We will assess GP antibiotic prescribing behaviour and the effects of the following interventions:

1 Does webbased GP self directed learning and use of patient booklet in the consultation change GP antibiotic prescribing behaviour

2 Does training in CRP near patient testing change GP antibiotic prescribing behaviour

Secondary outcome

We will also assess

1 Patient complications after the interventions by measuring significant deterioration of illness.

2 Costeffectiveness of the interventions by measuring resource use.

3 Issues behind the successes, difficulties and limitations of implementing behaviour change using GP focus groups.

4 Patient perceptions of the process using patient interviews.

Study description

Background summary

This study is part of a programme of research into cough due to chest and other infections across 15 European countries, called GRACE. This part of the GRACE study will be carried out in 6 European countries and aims to improve antibiotic prescribing for acute cough in primary care.

Acute cough /lower respiratory tract infection (LRTI) is one of the commonest reasons why people seek health care and take antibiotics. The implications for use of precious health care resources and antibiotic resistance are considerable. There is a wide variation in antibiotic prescription in Europe, and based on what is known about how comparable patients are investigated and treated in different European countries, there is a need to identify educational programmes directed at clinicians and patients to determine whether they improve the management of acute cough.

Study objective

This study will compare antibiotic prescribing levels for practices trained via the GRACE INTRO programme (a self directed web based learning package combined with patient booklets), with those not trained, and in addition will determine whether the use of CRP tests (a test that can be performed in the surgery to help GPs decide who to give antibiotics to) are useful in targeting prescriptions to the correct patients. The aim is to see whether GP antibiotic prescribing behavior can be improved so that only those patients with chest infections that will really benefit from
antibiotics are prescribed them. We will assess antibiotic use, complications and costeffectiveness.

Study design

Up to 16.800 (maximum) patients will take part in this study throughout Europe.

GP practices will be randomised into 4 groups
1. routine care
2. routine care plus GP training into optimal antibiotic use and Patient education with booklet (INTRO Programme)
3. routine care and additional training about the use of CRP tests
4. INTRO Programme and training about the use of CRP tests

Practices will be invited to participate in the study across 8 European networks

Baseline Data Collection:
Prior to the intervention practices will provide an audit of antibiotic use for a minimum of 30 consecutive patients with
Lower Respiratory Tract Infection (LRTI) presenting to participating clinicians, using a very brief case report form. Prior
to their participation in the research each patient will be informed about the

research and consented. A minimum of 5 consecutive patients who have other RTIs will also be assessed to document whether relabeling LRTI could account for reduced antibiotic prescribing.

For the intervention, practices will be randomised into four groups and trained according to their randomisation group.

Post Intervention Data collection:
Practices will provide an audit for a minimum of 30 consecutive patients with LRTI presenting to participating clinicians using a case report form which will document use of antibiotics, of delayed prescription, of near patient tests (and why used), and the use of a booklet. Prior to their participation in the research each patient will be informed about the research and consented. All patients will be asked to complete a diary recording symptom duration and severity. A minimum of 5 consecutive patients who have other RTIs will also be assessed to document whether relabeling LRTI could account for reduced antibiotic prescribing.

Note Review:
One month after data collection we will also ask participating practices to allow local research staff to perform a note review of the patients to monitor complications, antibiotic use and hospital admission data.

Focus Groups:
After the intervention, patient and GP focus groups (and/or individual interviews) will be convened with a selection of
participating doctors to explore issues behind the successes, difficulties and limitations of implementing behavior
change in practices using the GRACE INTRO Programme with or without CRP tests.

Intervention

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Study burden and risks

Patients with LRTI will not suffer any greater risk than if they were managed in routine care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Aged 18 years and over
- Consulting with acute cough as the main symptom (up to and including 28 days duration) or those in whom the general practitioner suspects the presence of acute lower respiratory tract infection
- Who have provided written, informed consent to participate
- Able to fill out study materials

Exclusion criteria

nvt

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2010
Enrollment:	2100
Type:	Actual

Ethics review

Approved WMO Date:	02-09-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-02-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-05-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL32098.041.10