GRACE (Genomics to combat Resistance against Antibiotics in Community-acquired LRTI in Europe).Workpackage 10: Antibiotic Trial One

Published: 21-08-2007
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The aim is to understand which individuals benefit from antibiotics.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON33677

Source
ToetsingOnline

Brief title
GRACE AT ONE

Condition

- Skin and subcutaneous tissue disorders NEC
- 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 Martina Dorward

Source(s) of monetary or material Support: Europese Unie

Intervention

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

Outcome measures

Primary outcome

Primary outcome parameters.

1) Deterioration of illness.

We will document significant deterioration of illness - which is defined as a return to the doctor with a worsening symptoms, new symptoms, new signs, or requiring admission to hospital within four weeks after the first consultation which has been used as a workable definition in previous studies of respiratory tract infection in the community; this includes pneumonia following uncomplicated community-acquired LRTI, sepsis, acute cerebrovascular and cardiovascular disease, exacerbations of concomitant high-risk disease, or death.

2) Symptom severity and duration. Our other main outcome is based on a symptom diary, which uses a format similar to previous diaries, and is based on the premise that the main outcome should reflect when patients report symptoms are a problem. The diary has construct validity - good correlation with the validated Measure Yourself Medical Outcome Profile - is sensitive to change, and internally reliable (Cronbach*s alpha 0.75 i.e. in optimal range). Our main symptomatic outcomes will be the duration of symptoms rated moderately bad by patients, and the mean diary score for days 2 to 4 when symptoms are rated as the worst problem by patients. Before day 2 antibiotics will have little chance

to provide benefit, and after day 4 on average symptoms are less than a moderate problem.

Secondary outcome

Other outcome parameters:

Resource use data from the societal perspective will be documented - based on review of the clinical notes. We will also collect quality of life outcomes for use of economic evaluation (the EQ5D will be filled in at the end of each week of the symptom diary)

Study description

Background summary

This study is part of a programme of research into cough and chest infections across 10 European countries, called GRACE. It is funded by the European Union. GRACE stands for *Genomics to combat resistance against antibiotics in community acquired lower respiratory tract infections in Europe*. GRACE aims to better understand what causes cough and chest infections and find ways of improving treatment.

Study objective

The aim is to understand which individuals benefit from antibiotics.

Study design

A randomised placebo-controlled trial will be performed in twelve primary care networks in 10 countries across Europe. 1500 Patients between 18 and 60 years old and 1500 older than 60 years of age will be randomised to either amoxicillin or placebo. This study (GRACE WP10) will be nested within another study, named GRACE WP9 (see ABR number 18455).

Intervention

Patients will be randomised to receive either antibiotic (amoxicillin 1g tid) or placebo for 1 week.

Study burden and risks

The patients who will receive amoxicillin can experience the usual side-effects of penicillin: it can cause nausea or diarrhoea, and sometimes it can cause a transient skin rash.

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 to 60 years and 60 years and over (enrolment will be done in such a way that 1500 patients under 60 and 1500 patients of 60 years and older will be included)
- 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 is immuno-competent (no serious immunological deficiencies)
- Who have provided written, informed consent to participate
- Who has not been on antibiotic treatment in the previous month

Exclusion criteria

Allergic to penicillin or a contra-indication for amoxicillin because of a major interaction with other medication
History/psysical examination suggestive of community acquired pneumonia (CAP)
pregnant

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2007
Enrollment:	300
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Amoxycillin
Generic name:	Amoxycillin

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	21-08-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-10-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-11-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-06-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-10-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-11-2009
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
EudraCT	EUCTR2007-001586-15-NL
CCMO	NL18456.041.07