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Genomics to combat Resistance against Antibiotics for Community acquired lower respiratory tract infection (LRTI) in Europe: INternet Training for Reducing antibiOtic use trial

Submission date 07/07/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/07/2010	**Overall study status** Completed	
Last Edited 15/04/2020	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Study website
https://www.grace-lrti.org/portal/en-GB

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8156

Study information

Scientific Title
Genomics to combat Resistance against Antibiotics for Community acquired lower respiratory tract infection (LRTI) in Europe: INternet Training for Reducing antibiOtic use - a multicentre randomised interventional process of care trial

Acronym
GRACE INTRO

Study objectives
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.

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 cost-effectiveness. Up to 5400 patients will take part in this study throughout Europe.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South West Hampshire Research Ethics Committee A, 13/05/2010, ref: 10 /H0502/29

Study design
Multicentre randomised interventional process of care trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
GP practices will be randomised into 4 intervention 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 C-reactive protein (CRP) test
4. INTRO Programme and additional CRP test

Antibiotic prescribing for LRTI will be audited for the practices pre- and post-intervention over one winter season.

Study entry: registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Antibiotic prescribing, measured at baseline and after intervention

Secondary outcome measures
1. Patient complications after the interventions by measuring significant deterioration of illness
2. Cost effectiveness 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

Overall study start date
01/10/2010

Completion date
01/05/2011

Eligibility

Key inclusion criteria
1. Aged 18 years and over, either sex
2. An illness where a acute cough or worsened cough is the main or dominant symptom, or a clinial presentation suggesting LTRI, greater than or equal to 28 days duration
3. First consultation for this illness episode
4. Seen within normal consulting hours
5. First time in this study
6. Ability to fill out study materials
7. Written consent to participate
8. Immunocompetent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 19600; UK sample size: 4900

Key exclusion criteria
Patients who are unable to properly consent or fill out the diary (dementia, psychosis, severe depression)

Date of first enrolment
01/10/2010

Date of final enrolment
01/05/2011

Locations

Countries of recruitment
Belgium

England

Netherlands

Poland

Spain

United Kingdom

Study participating centre
Primary Medical Care
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Clinical Neurosciences Division
Memory Assessment and Research Centre
Moorgreen Hospital
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Sponsor type
University/education

Website
http://www.soton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name

European Commission (Belgium) - The Sixth Framework Programme (FP6) (ref: LSHM-CT-2005-518226)

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?
Results article	results	05/10/2013		Yes	No
Results article	results	01/03/2019	15/04/2020	Yes	No