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Electronically delivered, multi-component intervention to reduce unnecessary antibiotic prescribing in primary care

Submission date
11/11/2014

Recruitment status
No longer recruiting

Registration date
18/11/2014

Overall study status
Completed

Last Edited
25/03/2019

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Antibiotics are vitally important medicines. They are used to treat infections caused by bacteria, some of which would otherwise kill the person affected. In recent years, however, antibiotic resistance, a situation where an antibiotic no longer works against one or more bacteria, has become a major problem. It has been caused by a number of factors, including general practitioners (GPs) prescribing them for minor illnesses that do not need them or for conditions that antibiotics cant cure (such as the common cold). Here, we are going to test whether an electronically delivered, multi-component intervention can reduce the number of unnecessary antibiotic prescriptions given to patients that go to their GP about a respiratory tract infection (RTI an infection of the sinuses, throat, airways or lungs).

Who can participate?
General practices that contribute up-to-standard data to the Clinical Practice Research Datalink (CPRD), the NHS observational data and interventional research service.

What does the study involve?
Participating CPRD general practices are randomly allocated into one of two groups. Those in the control group continue with their usual clinical care. Those in the interventional group receive an intervention made up of a number of parts. These include feedback on their rate of antibiotic prescribing compared to other GP practices, educational and decision support tools to support the none prescribing or delayed prescribing of antibiotics, and three minute webinars that explain and promote the use of the materials they are given. The study is run for 12 months, after which the antibiotic prescribing rates between the intervention and control groups are made, along with other outcome measures such as RTI consultation rate, health care costs, number of cases of pneumonia and lower respiratory tract infections and hospital admissions.

What are the possible benefits and risks of participating?
This research looks at inappropriate and unnecessary prescribing of antibiotics to patients with respiratory tract infections (RTIs) in general practice. All management decisions for individual patients remain at the discretion of individual general practitioners. Therefore, we do not

anticipate any potential serious adverse events that could be directly caused by the intervention. However, we will ask general practitioners at participating general practices to tell us of any possible adverse events.

Where is the study run from?
Kings College London (UK)

When is the study starting and how long is it expected to run for?
January 2015 to December 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Professor Martin Gulliford

Contact information

Type(s)
Scientific

Contact name
Prof Martin Gulliford

Contact details
King's College London
Department of Primary Care and Public Health Sciences
Capital House
52 Weston Street
London
United Kingdom
SE1 3QD
+44 (0)2078486631
martin.gulliford@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13/88/10

Study information

Scientific Title

Electronically delivered, multi-component intervention to reduce unnecessary antibiotic prescribing in primary care. Cluster randomised trial using electronic health records (eCRT2)

Acronym
eCRT2

Study objectives
To test the effectiveness, in a cluster randomised controlled trial, of electronically delivered, multi component interventions to reduce unnecessary antibiotic prescribing when patients consult for respiratory tract infections (RTI) in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES London Dulwich, 08/10/2014, ref. 14/LO/1730.

Study design
Cluster randomised trial with general practices as the unit of allocation

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Antibiotic prescribing/respiratory tract infections

Interventions
There will be two trial arms.
1. The control trial arm practices will continue with usual clinical care.
2. Practices in the Intervention trial arm will receive complex multi-component interventions, delivered remotely, as follows:
2.1. Feedback of each practices antibiotic prescribing results in relation to peers, through monthly updated antibiotic prescribing reports estimated from CPRD data
2.2. Delivery of educational and decision support tools to support policies of no-antibiotic prescribing or delayed prescribing
2.3. Three minute webinars to explain and promote effective utilisation of the intervention materials. The intervention will continue for 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Number of antibiotic prescriptions for RTI per 1,000 registered patient years at 12 months follow-up

Secondary outcome measures
1. Number of consultations for RTI with antibiotic prescribed / Total RTI consultations (%) at 12 months follow-up
2. Consultations and prescriptions as defined above during 14 days after the index consultation at 12 months follow-up
3. Number of consultations for RTI per 1,000 registered patient years 12 months follow-up
4. All antibiotic prescriptions per 1,000 registered patient years at 12 months follow-up
5. Number of hospital admission (by category) per 1,000 registered patient years at 12 months follow-up
6. Estimated costs of all health care utilisation per 1,000 registered patient years at 12 months follow-up
7. Broad categories of RTI subgroups including colds, sore throat, cough and bronchitis, otitis media and rhino-sinusitis (NICE, 2008) at 12 months follow-up
8. Number of adverse events ((peritonsillar abscess, mastoiditis, skin infections and bacterial infections) (by category) per 1,000 registered patient years over at 12-months follow-up

Overall study start date
01/01/2015

Completion date
31/12/2018

Eligibility

Key inclusion criteria
General practices will be included in the trial if:
1. They presently contribute up-to-standard data to CPRD
2. Consent to participation in the trial
3. Are located in areas that have given research governance approval for the study

Data for non-trial CPRD practices will be eligible for observational data analysis to gauge the representativeness of practices and patients participating in the trial.
Data for individual participants will be included if they are currently registered with CPRD general practices

Participant type(s)
Patient

Age group

Other

Sex
Both

Target number of participants
120

Key exclusion criteria
No other exclusion criteria

Date of first enrolment
01/01/2015

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE1 3QD

Sponsor information

Organisation
National Institute for Health Research (UK)

Sponsor details
Evaluation, Trials and Studies Coordinating Centre
University of Southampton
Alpha House, Enterprise Road
Southampton
United Kingdom
SO16 7NS

Sponsor type
Government

Website
http://www.nets.nihr.ac.uk/programmes/hta

ROR
https://ror.org/0187kwz08

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme (Ref: 13/88/10)

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/12/2019

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	04/08/2016		Yes	No
Results article	results	01/03/2019		Yes	No

HRA research summary	28/06/2023	No	No