

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

Submission date 11/11/2014	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 18/11/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/03/2019	Condition category Infections and Infestations	☐ 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 can't 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

Protocol serial number
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.

Primary study design

Interventional

Study design

Cluster randomised trial with general practices as the unit of allocation

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

United Kingdom

England

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

Sponsor information

Organisation
National Institute for Health Research (UK)

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, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2019		Yes	No
Protocol article	protocol	04/08/2016		Yes	No
HRA research summary			28/06/2023	No	No