ISRCTN83234896 https://doi.org/10.1186/ISRCTN83234896

A program to optimize the quality of antibiotic use within the hospital - impact on antibiotic consumption, cost savings and bacterial resistance

Submission date
24/04/2012

Recruitment status
No longer recruiting

Registration date
08/05/2012

Overall study status
Completed

Last Edited
12/06/2017

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Antibiotics are a very large and growing percentage of pharmaceutical spending that can reach 30% of the cost of a hospital pharmacy. The excessive and inappropriate use of antibiotics is of great importance due to the cost and undesirable side effects, and the growing development of resistance to antibiotics. Control measures aimed at optimizing the prescription of antibiotics can generate significant savings, improve patients' prognosis and reduce resistance to antibiotics. As a result, in recent years, numerous hospitals have designed different models to achieve this objective.
The aim of this study is to assess the impact of an intervention to optimize the use of intervention in a hospital.

Who can participate?
Patients admitted to General Surgery, Pneumology and Endocrinology at the Hospital Universitario Marqués de Valdecilla (Spain), and prescribed antibiotics by their doctors for more than 3 days

What does the study involve?
The participating clinical units are randomly allocated to either receive the intervention or to not receive the intervention. The intervention consists of treatment recommendations written by an infectious diseases physician based on international treatment guidelines, adapted after examination of patients, clinical records and microbiological data (if any) for each patient in the intervention group. Written recommendations (in specifically designed study forms) are inserted into the patient's records to make them available to treating physicians, with a statement indicating their availability for oral consultation if desired. Consultation is also available as part of daily practice for physicians treating patients in the non-intervention group (without insertion of written recommendations), but in this case the patient is withdrawn from the study. Demographic and clinical data (including other illnesses), antibiotic treatment given, reason for antibiotic treatment, imaging and microbiological data, and microbiological and clinical

outcomes are recorded for patients in both groups. Length of hospitalization (time from admission to discharge/death) is calculated. On the 7th day, adherence to the treatment recommendation is assessed. The microbiological and clinical outcomes of infections are assessed at the end of antibiotic treatment and at discharge.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Training and Research Institute, Marqués de Valdecilla (Spain)

When is the study starting and how long is it expected to run for?
January 2007 to June 2009

Who is funding the study?
1. Ministry of Health (Spain)
2. Training and Research Institute Marqués de Valdecilla (Spain)

Who is the main contact?
Prof. M. Carmen Fariñas

Contact information

Type(s)
Scientific

Contact name
Prof M. Carmen Fariñas

Contact details
Avd. Valdecilla s7n
Santander
Spain
39008

Additional identifiers

Protocol serial number
API 06/03-PI06/90094

Study information

Scientific Title
A PRogram to Optimize the quality of Antibiotic use within the hospital - impact on antibiotic consumption, cost savings and bacterial resistance: a randomized controlled study

Acronym
PROA

Study objectives

The prevalence of use of antimicrobial drugs in the hospital setting is very high. The economic cost involved is considerable and growing, and can be up to 30% of the cost of a hospital pharmacy. However, several studies have estimated that more than half of the prescriptions of antimicrobials in the hospital setting are inappropriate. This is not only for important economic consequences, but also clinics, which are drugs with a relevant role in the prognosis of patients and not free of side effects. But also its excessive and inappropriate use is linked to the unstoppable increase of antibiotic resistance to which we have been witnessing in recent years.

Implementation of a randomized controlled intervention with blind from the same analysis, aimed at optimizing the use of antimicrobial drugs in certain units of a tertiary hospital will reduce consumption and associated spending, improve the quality of the prescription and decrease the number of resistance to them.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Hospital Universitario Marqués de Valdecilla, Santander, Spain, 24/05/2006
2. Clinical Investigation Committee of Community of Cantabria, 19/05/2006

Study design
Randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients on antibiotic therapy

Interventions
Patients with 3 day antibiotic treatment will be identified by the pharmacy service daily from Monday to Friday. Once checked the inclusion criteria, there will be the randomization stratified by clinical units, through the generation of random numbers generated by computer. The fellow of the project will come to review clinical data of the patient and shall obtain the microbiological data to the microbiology service the same day in which the case has been identified.Then, in the intervention group, under the advice of researchers in the team, will develop a simple and concise, recommendations on the use of antimicrobials in the specific case: suspension of the / the same, modification of dose, route of administration, change of antimicrobial modification / s, obtaining of levels in a standardized written form, developed specifically for this purpose, that it will be included in the active medical history of patient, to be included in the active clinical history of the patient. The recommendations will include a phone contact so that the responsible clinician can, if desired, please contact with the fellow. Initially intervention will be leave to the recommendations in writing, though it can occur is to comment verbally to the prescriber. The fellow in no case will directly make the prescription.Recommendations will focus, above all, on the following:

1. Correct indication of antibioterapia
2. Boost sequential therapy and reduce unwarranted use of parenteral antibiotic

3. Adequacy of the treatment identified microorganisms
4. Proper dosage and duration

These recommendations will be based on the recommendations and guidelines on the use of antibiotics published in literature, as well as with the rules established by the Commission of Hospital infections. With these fundamentals, the team shall draw up common guidelines to guide recommendations.

In this first visit to the patient will be collected data concerning the patient, reason for the antibiotic indication and made recommendation. Day 7 after the start of antimicrobial treatment will be a second visit to the patient in which data concerning adherence to the recommendation made on the first visit will be collected. If the 7 day is convenient to make a new recommendation will take place in the same way as the previous. In the 48-72 hours will evaluate whether or not there has been adherence to the recommendation.

Infectious Diseases Consultation was also available as part of daily practice for physicians treating patients in the non-intervention group (without insertion of written recommendations), in this case the patient was withdrawn from the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. To know the current situation of antibiotic use in the Valdecilla Hospital
2. To evaluate the impact of an intervention designed to optimize the antibiotic consumption and cost, as well as the incidence of bacterial resistance in some hospitalization units

Key secondary outcome(s))
1. To analyze the impact of the intervention on the microbiological and clinical prognosis of patients, as well as half of them stay
2. To investigate the adhesion of medical intervention and the impact of such adherence on the microbiological and clinical prognosis of patients
3. To investigate if the results obtained with the intervention are maintained over time

Completion date
30/06/2009

Eligibility

Key inclusion criteria
Patients:
The reference population is composed of patients admitted in the Hospital Universitario Marqués de Valdecilla with antimicrobial treatment prescribed by their responsible doctors for more than three days.
The clinical services/units in which the study will be realized will comply with the following criteria for inclusion:

1. Stability in the physicians who participate in the study
2. Stability in the number of beds and type of assisted
3. Agreement by doctors who work in them to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Pediatric patients
2. Patients with terminal chronic renal failure (on dialysis)
3. Patients with oral antibiotic treatment
4. Antibiotic treatment already prescribed by the Infectious Diseases Unit
Patients whose antibiotic has been prescribed by a member of the Infectious Diseases Unit as part of the usual care task shall be excluded from the study

Date of first enrolment
01/01/2007

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Spain

Study participating centre
Avd. Valdecilla s7n
Santander
Spain
39008

Sponsor information

Organisation
Training and Research Institute, Marqués de Valdecilla (Spain)

ROR
https://ror.org/025gxrt12

Funder(s)

Funder type
Government

Funder Name
Ministry of Health (Spain) - Fondo de Investigaciones Sanitarias (ref: FIS PI06/90094)

Funder Name
Training and Research Institute Marqués de Valdecilla (Instituto de Formación e Investigación Marqués de Valdecilla) (IFIMAV) (Spain) (ref: API 06/03)

Results and Publications

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	09/11/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes