Reduction of human exposure to resistant micro-organisms: a Pragmatic approach - the RedRes-study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON36772

Source ToetsingOnline

Brief title RedRes-study

Condition

• Bacterial infectious disorders

Synonym

CD carriership, degree of antimicrobial resistance, ESBL carriership, MRSA carriership

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Utrecht **Source(s) of monetary or material Support:** Ministerie van OC&W,ZonMw

Intervention

Keyword: Antimicrobial resistance, Clostridium difficile (CD), Extended-Spectrum &beta, -Lactamases (ESBLs), Methicillin-Resistant Staphylococcus aureus (MRSA)

Outcome measures

Primary outcome

The primary parameters are the prevalence of nasal MRSA carriage, the

prevalence of ESBLs and CD in faecal samples, and the degree of antimicrobial

resistance in faecal samples.

Secondary outcome

One secondary parameter is the prevalence of MRSA, ESBLs, CD and the degree of

antimicrobial resistance in environmental samples. Data on potential

confounding factors (such as age of animals, hygiene compliance, change in

contact structure etc.) will be collected as well.

Study description

Background summary

Intensively reared farm animals (veal calves, pigs and poultry) form a reservoir for antimicrobial resistant bacteria and antimicrobial resistance genes. Antimicrobial use is generally regarded as one of the main reasons for the selection and spread of resistant bacteria. In order to reduce the prevalence of resistant bacteria in farm animals, and thus to reduce this public health threat, interventions should be implemented at farm level and should be aimed at reduction of antimicrobial use, improving hygiene, and changing animal contact structure. It is hypothesized that these measures will limit transmission of antimicrobial resistant organisms between different compartments, similar to infection control measures in (human) health care settings, and subsequently will result in a significantly reduced prevalence of resistant bacteria on farms. So far, no research has been done on the possible effect of these potential intervention measures. Therefore, it is unclear what the quantitative effect of possible intervention measures is on the level of antimicrobial resistance on the farm, both in animals and in humans. In order

to create an adequate and effective control and intervention protocol for antimicrobial resistance, this quantitative knowledge is essential.

Study objective

Primary objectives:

1. To determine the effect of the use of a tailored intervention protocol (regarding reduced antimicrobial use, improving hygiene and changing the animal contact structure) on pig and veal farms on the degree of antimicrobial resistance and the prevalence over time of MRSA, ESBLs and CD in people working and/or living on these farms.

2. To determine the effect of the use of a tailored intervention protocol (regarding reduced antimicrobial use, improving hygiene and changing the animal contact structure) on pig and veal farms on the degree of antimicrobial resistance and the prevalence over time of MRSA, ESBLs and CD in animals on these farms.

3. To determine the effect of the use of a tailored intervention protocol (regarding reduced antimicrobial use, improving hygiene and changing the animal contact structure) on pig and veal farms on the degree of antimicrobial resistance and the prevalence of MRSA, ESBLs and CD in the stables and living environment.

Secondary objectives:

1. To determine the prevalence of LA-MRSA in pigs and veal calves as well as in humans at the beginning of the study using nose swabs.

2. To determine the prevalence of ESBLs, CD and the degree of antimicrobial resistance in pigs and veal calves as well as in humans at the beginning of the study by using faecal samples.

3.To determine the prevalence of LA-MRSA, ESBLs, CD and the degree of antimicrobial resistance in the stables and living environment at the beginning of the study using electrostatic dust cloths.

4. To describe associations between antimicrobial resistance in animals and antimicrobial resistance in humans by means of (dynamic mathematical) modelling.

5. To predict antimicrobial resistance throughout the pig- and veal production chain under different intervention scenarios.

Study design

We will perform a pragmatic intervention study which makes use of repeated measurements to determine the effect of a reduction in antimicrobial use on 40 pig farms and 51 veal farms on the level of antimicrobial resistance in humans and animals on these farms. This reduction in antimicrobial use will be indirectly achieved by influencing animal contact structure and hygiene protocols, and directly by reducing antimicrobial use.

The farms and the individual participants will be monitored during 18 months. There will be 4 sampling moments. At each sampling moment a nasal swab and a faecal sample will be taken by all the participants themselves. Also, at each sampling moment a questionnaire will be filled out by the participants. MRSA will be determined in the nasal swabs and ESBLs, CD, and the degree of antimicrobial resistance will be determined in the faecal samples.

Intervention

In this study, interventions on reduced antimicrobial use, improved hygiene and changed animal contact structures will take place at farm level and therefore in the animals.

Study burden and risks

Participation in the study does not take much time and there will be no invasive procedures used. In a study period of 18 months there will be 4 sampling moments. At each sampling moment a nasal swabs and a faecal sample will be taken by all the participants themselves, which should not be considered to be much discomfort to the participants. Also, at each sampling moment a questionnaire will be filled out by the participants. The risks of participation in this study can be considered negligible and the burden can be considered minimal. To estimate prevalence within one household, it is necessary that all household members and employees of the included pig and veal farmers (inclusive minors and incapacitated individuals) will be examined for colonization of MRSA, the degree of antimicrobial resistance and the occurrence of ESBLs and CD.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Children (2-11 years) Elderly (65 years and older)

Inclusion criteria

Working or living on an pig or veal farm

Exclusion criteria

not applicable

Study design

Design

Study type: Observational non invasiveMasking:Open (masking not used)Control:UncontrolledPrimary purpose:Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-04-2011
Enrollment:	364
Туре:	Actual

Ethics review

Approved WMO	
Date:	04-04-2011
Application type:	First submission
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 CCMO ID NL35035.041.10