Spread of veterinary MRSA in The Netherlands

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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-OMON32156

Source
ToetsingOnline

Brief title
SPREAD study

Condition

- Bacterial infectious disorders
- Economic and housing issues

Synonym
non-typable MRSA, pig-MRSA

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: eigen bijdrage

Intervention

Keyword: prevalence, risk factors, spread, veterinairy MRSA

Outcome measures

Primary outcome

The prevalence of V-MRSA in areas with high density of pig farming compared to the prevalence of MRSA in the general population of The Netherlands. This is primarily determined by the amount of individuals colonized with V-MRSA. An individual colonized with V-MRSA is defined as case. However, subjects colonized with HA-MRSA will be excluded. Prevalence of V-MRSA is calculated by dividing the total number of cases by the total number of participants.

Secondary outcome

The amount of spread of V-MRSA into the population of The Netherlands.

Prevalence of 2% or more is considered to be a significantly increase of the expected MRSA prevalence of 0.5%.

Study description

Background summary

Traditionally, meticillin resistant Staphylococcus aureus (MRSA) has been considered as a hospital associated pathogen. Since approximately 10 years, MRSA has expanded its territory to the community causing severe infections in previously healthy persons all over the world. In 2005 a new clone of MRSA was observed in The Netherlands that is related to an extensive reservoir in pigs and cattle (V-MRSA). A survey among pigs at slaughterhouses showed that 40% of all pigs were colonized with MRSA. By the end of 2007, approximately 30% of all new MRSA strains in The Netherlands were V-MRSA.
Individuals who are living on animal farms but not in direct contact with animals had a lower carriage rate (approximately 2%). A recent survey among meat in retail showed that nearly 10% harbored V-MRSA. V-MRSA may spread into the population from direct or indirect contact with animal farms or from

handling or consuming contaminated meat. The first transmission route is considered most likely and will occur first in areas with a high density of pig farms. The second route (meat) is considered less likely but may have much larger impact.
The prevalence of MRSA in the general population of The Netherlands was in 2007 still very low (<0.5%). If V-MRSA can successfully spread from human to human outside the known high risk group into the population it will constitute a significant public health problem in the near future. This will necessitate major adaptations of the existing guidelines for control in the community and in healthcare institutions. It is questionable if the current control strategy in The Netherlands can be maintained in this scenario. At least the associated costs will increase significantly. The public health impact of V-MRSA will depend mainly from its ability to spread in the population outside animal farms.

Study objective

The primary objective of this study is to determine the prevalence of V-MRSA in areas with high density of pig farming compared to the expected prevalence of MRSA in the general population of The Netherlands and as a secondary objective to assess the amount of spread of V-MRSA into the population of The Netherlands.

Study design

1500 randomly chosen individuals will be sent a short questionnaire, a patient information letter and informed consent by mail. Participation of subjects is voluntary and based on informed consent. Subjects are also asked to approve a sampling and that they can be contacted afterwards for an extensive questionnaire. After the written informed consent is obtained, participants will subsequently be sent a nasal swab which can be returned by mail in the appropriated packaging. The swabs will be sent and cultured for the presence of MRSA at the several laboratories. A total of approximately 600 samples will be included in the study initially. Furthermore, Multi-locus variable-number tandem-repeat analysis (MLVA) and the spa typing of the V-MRSA strains will be performed at the RIVM. When MRSA prevalence of 2% or more is found the study will be continued by phase two.
In the second phase a nested case-control study will be performed based on the first survey to identify determinants for
V-MRSA carriage in relation to animal farms and handling and/or consuming meat. Individuals who are colonized with
V-MRSA are compared with individuals who are not colonized with V-MRSA strains. In addition, subjects with HA-MRSA will be excluded. All selected subjects will be sent a questionnaire. At least the following variables will be included in the questionnaire: Age, gender, contact with animals (which kind and how often), presence of animals in the house, preparation and/or consumption of

meat (which kind and how often), antibiotic use in the last six months, underlying disorders (e.g., eczema, psoriasis or other skin diseases, lung diseases (COPD), allergy, recurrent upper respiratory tract infections, malignancies, immunosuppressive drugs, foreign bodies, history of recurrent furunculosis), history of MRSA infection and/or colonization, profession, being active in a contact sport, household member working on an animal farm and presence of indwelling catheters and/or open wounds.
If the results of phase one indicate spread of V-MRSA into the community a similar survey is performed in several communities with an extremely low density of animal farms. This survey is mainly focused on the potential spread from contaminated meat.

Study burden and risks

Participation in the study does not take much time and there are no invasive procedures. Altogether, only one nose swab sample will be taken and will be sent to one of the collaborated laboratories for identification of MRSA. Taking nose swab should not be considered to be much discomfort to the subjects. Furthermore, two questionnaires will be taken to identify determinants for MRSA carriage in relation with direct animal contact and consumption and/or preparation of contaminated meat. There will be no physical or physiological discomfort, no site visits and no physical examinations or other tests associated with participation. Therefore, participation in the study will not involve any substantial risk for the included subjects and the investigators will not interfere with treatment.

Contacts

Public
Amphia Ziekenhuis

Molengracht 21
4800 RK BREDA
Nederland
Scientific
Amphia Ziekenhuis

Molengracht 21
4800 RK BREDA
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Addressed individuals are 18 years or older

Exclusion criteria

- Living on a farm with pigs or veal calves
- Professional contact with pigs or veal calves

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-07-2008
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	16-06-2008
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	ID
CCMO	NL23112.008.08