Characterization of veterinary and community acquired MRSA: determinants, transmissibility and virulence

Published: 04-12-2007
Last updated: 11-05-2024

The objective of this study is to identify determinants, to determine the transmissibility and to determine the burden of disease of NT-MRSA and CA-MRSA carriage compared to other typeable MRSA strains in the community.

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

Summary

ID

NL-OMON33751

Source
ToetsingOnline

Brief title
VET.CAM study

Condition

- Bacterial infectious disorders

Synonym
hospital bacteria, MRSA

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: determinants, MRSA, transmissibility, virulence

Outcome measures

Primary outcome

The difference in transmissibility of NT-MRSA and CA-MRSA compared to T-MRSA. This is primarily determined by the prevalence of secondary cases among household members (secondary attack rate). A secondary case is defined as a household member that carries the same molecular type of MRSA as the index-case. The prevalence of transmission is calculated by dividing the total number of secondary cases by the total number of susceptible household members. Furthermore, the determinants of NT-MRSA and CA-MRSA carriage will be defined using a questionnaire. The prevalence of these determinants will be compared with HA-MRSA carriage and non-MRSA carriage.

To determine the virulence of NT-MRSA and CA-MRSA the occurrence of infections caused by these MRSAs are compared. Also the occurrence of medical events in general and the use of antimicrobial agents is measured. The burden of disaese will be measured using four short self-administrated questionnaires. Adjustment for factors that may affect the occurrence of disease will be applied using regression analysis.

Secondary outcome

not applicable

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. Although community-acquired MRSA (CA-MRSA) infections are usually mild, they may also be severe, and can result in hospitalisation and even death. In The Netherlands there is an increasing number of individuals who are identified as carriers of MRSA that do not belong to known risk groups, indicating a new source outside of the hospital. To define preventive interventions in the community and to improve the control measures in hospitals and nursing homes more knowledge is needed on the reservoirs and transmission routes in the general population.
Furthermore, in 2003 a new clone of MRSA was observed in The Netherlands that is related to an extensive reservoir in pigs and cattle. A survey among pigs at slaughterhouses showed that 40% of all pigs were colonized with MRSA. This clone is characterized by being non-typable by the typing method that is used at the Dutch national reference laboratory at the RIVM and therefore is named non-typable MRSA (NT-MRSA). By the end of 2007, 30% of all new MRSA strains in The Netherlands were NT-MRSA.
At present it is unclear whether NT-MRSA is easily transmissible from human to human. Considering the extensive reservoir in animals and people who work with these animals, there are at present relatively few cases of NT-MRSA in people who are not directly related to farming. If NT-MRSA is hardly transmissible from human to human this would limit the public health impact and the control measures in health care facilities could probably be less stringent.

Study objective

The objective of this study is to identify determinants, to determine the transmissibility and to determine the burden of disease of NT-MRSA and CA-MRSA carriage compared to other typeable MRSA strains in the community.

Study design

Members of the VGV and newly found MRSA patients who are colonized with T-MRSA will be asked to take a nasal and throat swab and return these by mail to a central laboratory. All included subjects will be visited by the investigator or a research nurse. The eligibility is checked and written informed consent is obtained from all the household members. A questionnaire is taken to collect demographic data and information on risk factors for MRSA infection/colonization. Subsequently, a specimen for culture from both anterior nares, the throat and skin lesions if applicable from all household members

will be obtained.
All subjects and their household members will be followed for the occurrence of medical events during one year. This includes the development of infections with MRSA, antibiotic use and other significant medical events. The sampling will be repeated after 4, 8 and 12 months. The material and instructions for sampling at 4 and 8 months will be delivered at the intake visit together with a short questionnaire. Participants will be asked to take samples from nares and throat and sent them together with the questionnaire to the central laboratory. At 12 months the investigator or the research nurse will visit the participants again and will take microbiological samples from nose and throat and a final medical questionnaire.

Study burden and risks

Participation in the study does not take much time and there are no invasive procedures. Altogether, nose and throat swab samples will be taken four times from all subjects and their household members and will be send to the Amphia Hospital Breda, Laboratory for Microbiology and Infection Control for identification of MRSA. Taking nose and throat swabs should not be considered to be much discomfort to the subjects.
Also, all samples will be typed using three different typing methods. Amplified-fragment length polymorphism (AFLP) analysis will be performed at the VUmc. Multi-locus variable-number tandem-repeat analysis (MLVA) and the spa typing will be performed at the RIVM. Furthermore, during the one year follow-up period questionnaires are taken four times, which are four short questionnaires each period. At the beginning and at the end of the study two extensive questionnaires will be taken. 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

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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

- Index-cases of any age are eligible
- Index-cases have at least one household member (only applicable for VET study)
- Household members of any age are eligible

Exclusion criteria

- Living on a farm with pigs or veal calves
- Professional contact with pigs or veal calves by the household members
- Treatment for colonization of MRSA in the last 3 months of the index-case or any of the household members
- Living in a nursing home or other healthcare facility
- Persons who are no patients, for example MRSA positive health care workers of the participating hospital
- Persons living abroad (only appicable for CAM study)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2008
Enrollment:	1250
Type:	Actual

Ethics review

Approved WMO Date:	04-12-2007
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	26-02-2008
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	11-08-2008
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	01-03-2010
Application type:	Amendment
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	NL19489.008.07