

# Methicillin-resistant Staphylococcus aureus: Occupational exposure, dynamics of carriage and associated disease in livestock farmers and their household members.

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Primary objective: To determine the dynamics of MRSA carriage in persons working on or living at pig and veal farms. Secondary objectives: To determine the amount of disease associated with carriage of MRSA-CC398. To determine the role of exposure to...

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

## Summary

### ID

NL-OMON33440

### Source

ToetsingOnline

### Brief title

POM-study

### Condition

- Bacterial infectious disorders

### Synonym

hospital bacteria, MRSA

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Sint Elisabeth Ziekenhuis

**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** carrier state, livestock, MRSA, occupational risk

## Outcome measures

### Primary outcome

The primary outcome is the prevalence of persistent MRSA carriage in primary versus secondary exposed persons. A secondary case is defined as a household member that carries MRSA-CC398 on a farm where MRSA was found during the study period. Persistent carriage is defined as all samplings being positive for MRSA, intermittent carriage is defined as 1 to 5 out of 6 samples positive. If none of the samples return MRSA it is referred to as non-carriage. Adjustment for factors that may influence persistent carriage, e.g. carriage of methicillin susceptible *S. aureus* (MSSA), throat carriage, the amount of MRSA present in the nose or throat and the presence of MRSA in wounds or skin diseases will be done. Furthermore, the association between the number of positive samples during the initial 3 swabs and the carriage status at 4, 8 and 12 months is determined. This is done for both MSSA and MRSA.

### Secondary outcome

To determine the amount of disease associated with carriage of MRSA-CC398 the occurrence of medical events will be recorded. Not only infections caused by MRSA are included in this follow-up but also visits to the general practitioner, use of antibiotics, hospital admissions etc. Adjustment for

factors that may affect the occurrence of disease will be done using regression analysis. Lastly the exposure to dust on MRSA positive farms will be studied, using information from questionnaires, personal dust samplers and environmental samples from house and stable.

## Study description

### Background summary

Traditionally, methicillin-resistant *Staphylococcus aureus* (MRSA) has been considered a hospital related pathogen. More recently, MRSA has emerged in the community as well. Recently a specific clone, MRSA-CC398, has been discovered, which is coming from an extensive animal reservoir. Initial surveys have shown a high prevalence of carriage in livestock farmers (up to 30%) and lower carriage rates in people living on farms but with limited direct contact with the animals (up to 4%). MRSA has also been recovered from more than 10% of retail pork and 16% of veal calf meat samples in The Netherlands. However, the exact consequences of this reservoir to public health are at present unknown, as no research has been done so far to reveal the dynamics of carriage and association with disease of MRSA-CC398 in livestock farmers and their household members.

### Study objective

Primary objective: To determine the dynamics of MRSA carriage in persons working on or living at pig and veal farms.

Secondary objectives: To determine the amount of disease associated with carriage of MRSA-CC398. To determine the role of exposure to dust in the environment on the occurrence of disease.

### Study design

In this study participants experience nasal and throat swabs, questionnaires and environmental samples. Part of the nasal swabs, questionnaires and environmental samples is taken by a trained representative of the study; another part is taken by the participant himself. Throat swabs will only be taken by trained representatives. In addition, blood samples will be taken on a voluntary base, in order to determine genetical features of MRSA-carriage. In some farms environmental samples will be validated by Anderson samplers. Moreover, direct exposed persons are equipped with a portable pump, in order to measure the dust and bacterial load during high risk tasks in the farm.

This study involves 3 sampling moments in the first week, and after this 1 sampling moment every 4 months ending 1 year after start of the study, adding up to a total of 6 sampling moments. At the beginning as well as at the end of the study, farms will be visited by a representative. The samples at moments in between will be taken by the participants themselves. For an overview, see the time schedule in the study protocol.

### **Study burden and risks**

Participation in the study does not take much time (30-60 minutes per sampling moment) and there are no invasive procedures. Altogether, 1 throat and 6 nasal swab samples will be taken from all subjects, these will be tested for presence of MRSA. Taking nose and throat swabs should not be considered to be much discomfort to the subjects. Blood samples can be taken on a voluntary base, and will not give much discomfort as well.

Furthermore, during the one year follow-up period questionnaires are taken at 6 moments. At the beginning and at the end of the study two extensive questionnaires will be taken. There will be no physical or psychological 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

Individuals of any age are eligible and should be:

1 - Working with pigs or veal calves on a farm (primary exposed)

or

2 - Living on a pig or veal farm and not working with the animals (secondary exposed)

### Exclusion criteria

- Treatment for colonization of MRSA in the last 3 months of any potential participant (farm will be excluded)

- Being colonized with other types of MRSA than CC398

## 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): 20-01-2010  
Enrollment: 200  
Type: Actual

## Medical products/devices used

Registration: No

## Ethics review

Approved WMO  
Date: 02-09-2009  
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	NL28121.008.09