

# Seroepidemiological and risk factor survey among Dutch livestock farmers (SBV-I) and veterinarians (SBV-II) exposed to Schmallenberg virus

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

## Summary

### ID

NL-OMON37557

### Source

ToetsingOnline

### Brief title

SBV-I & SBV-II

### Condition

- Viral infectious disorders

### Synonym

(Infection with) Schmallenberg/Schmallenbergvirus/SBV

### Research involving

Human

### Sponsors and support

**Primary sponsor:** RIVM

**Source(s) of monetary or material Support:** Ministerie van VWS

## **Intervention**

**Keyword:** livestock farmers, livestock veterinarians, ruminants, Schmallenberg virus (SBV)

## **Outcome measures**

### **Primary outcome**

Presence of antibodies against SBV in this study population together with the absence of antibodies in the historic reference samples from farmers and veterinarians (collected between 2006 and 2010) will be used as indication of past infection among livestock farmers and veterinarians.

### **Secondary outcome**

If seropositives are found, seropositivity is the outcome measure for the risk factor analysis. Risk factors include age, gender, individual direct exposure to infected ruminants - especially animals giving birth - use of protective clothing (gloves), risk perception, skin injuries when working with animals, consumption of raw milk or fresh dairy products, medical history, insect-bites etc.. Analysis will also include association of seropositivity with health complaints reported in the questionnaire.

## **Study description**

### **Background summary**

In early November 2011 a new orthobunyavirus, provisionally named the Schmallenberg virus (SBV), was detected in cattle with diarrheal disease in Germany. Early December, this virus was found in association with malformed lambs in The Netherlands. Since then, similar findings have been observed in sheep and cattle in the Netherlands, France, Belgium and the UK. Viruses of the family Orthobunyaviridae are segregated into genotypes and serogroups as

taxonomic units. The SBV belongs to the Simbu serogroup, that contains several other viruses causing similar syndromes in ruminants, but also some viruses that cause febrile illness (reportedly without congenital malformations) in humans. Therefore, the possibility that this virus would cause disease in humans cannot be excluded at this stage, although there are no indications from regular surveillance. Transmission of SBV most likely occurs through vectors such as midges and possibly mosquitos, and the current problems in cattle and sheep are related to a peak of infections during late summer. Humans may have been exposed during that time period as well. The birth of malformed sheep and cattle leads to increased manual contact of farmers and veterinarians during delivery, adding a second source of exposure as birthing material contains genetic material of SBV. If human infection would be possible, farmers and veterinarians in close contact with or living and working in the same area as infected animals are most likely to have been at risk.

### **Study objective**

The aim of this study is to do a sero-survey among farmers - including their family and employees - and veterinarians living and/or working with livestock and - if sero-positive cases would be found - to identify risk factors for sero-positivity and to evaluate the association of seropositivity with reported health complaints.

### **Study design**

This is a cross-sectional study among farmers - including their family members and employees - and veterinarians living around and/or working with livestock. Questionnaires and serum samples will be obtained from farmers from SBV-infected farms and veterinarians that worked at SBV-infected farms. Farmers will be enrolled in cooperation with the Animal Health Service; veterinarians attending the GGL conference in Doorn on March 28th 2012 will be enrolled if they report to have worked at SBV-infected farms. Samples will be screened using a SBV neutralisation test on Vero-e6 cells with SBV antigen. If positive samples are found, by the use of the questionnaires the risk factors associated with SBV seropositivity will be studied in this occupational group. Results will be compared with a historic reference sample set from the same risk groups.

### **Study burden and risks**

For the farmers, the burden for the participation of this study consists of:

- blood sampling through a single venapuncture to obtain a serum sample (2 tubes of 5 ml) per person at the participating farm by a research assistant from a municipal health service (maximum 10 minutes per person). The research assistant will make an appointment for the farm visit by phone. Research

assistants will perform blood sampling at the farm location in order not to burden the study participants with extra travel time.

- completion of an individual questionnaire for those providing a blood sample (approx 10 minutes). The research assistant will hand out the questionnaire during the farm visit and collect them at the end of the visit after checking for completeness..

- The complete farm visit of the research assistant will take approximately 1 hour (blood sampling and check for completeness of the individual questionnaires for 2 participants per farm).

For the veterinarians, the burden for the participation of this study consists of:

- Blood sampling through a single venapuncture to obtain a serum sample (2 tubes of 5 ml). In order not to burden the study participants with extra travel time, blood sampling will be performed at the GGL conference March 28th in Doorn by two research assistants. The participants receive study information at least one week in advance of the GGL conference, completion of a questionnaire (approximately 10 minutes). This will be checked by a research assistant for completeness.

Participation to the study is on a voluntary basis. The burden associated with participation is marginal. The risks are negligible as the study entails a single venapuncture carried out by a research assistant experienced in taking blood samples and the completion of a questionnaire. Physical examinations or other tests are not part of the study design. Study participants will be assigned an anonymous study ID which will be used to analyze and store the data. Results of the study will only be reported on a group level and cannot be deducted to the individual or to individual farms or practices. As indicated on the informed consent form, upon request participants can receive their test result if it is positive from the GGD, with microbiological interpretation and explanation.

## Contacts

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Working and/or living at a ruminant farm in the Netherlands that is notified as a SBV-infected farm.

### Exclusion criteria

None

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-03-2012
Enrollment:	400
Type:	Actual

## Ethics review

Approved WMO	
Date:	13-03-2012
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	ID
CCMO	NL39914.041.12