An integrated study on Q fever in livestock farmers and ruminant animals in the Netherlands

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Overall aim: to determine the extent and risk factors for farm-based and individual acquisition of Coxiella burnetii infections on ruminant farms to improve veterinary, occupational and public health by providing leads for primary (reduce...

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

Summary

ID

NL-OMON33109

Source
ToetsingOnline

Brief title
Q-VIVE

Condition

- Bacterial infectious disorders

Synonym
Balkan grippe, Coxiella burnetti infection, Query Fever

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: dairy cattle, farm environment, goat, livestock farmers, Q-fever, ruminants, sheep

Outcome measures

Primary outcome

Prevalence of C. burnetii past infections in the Netherlands among small ruminant farmers, their family members and relevant co-workers

Secondary outcome

Risk factors and determinants for C. burnetii past infections in the Netherlands among small ruminant farmers, their family members and relevant co-workers. Risk factors adressed in the farm-baeed questionnaire include farm hygiene and management, e.g. manure handling, handling of abortion products, housing conditions, vaccination status, rodent control, farm type, e.g. farm size, open/closed system, and animal health status, including tick infestation and abortions), and in the individual questionnaire adress age, gender, profession, degree of urbanisation, province, ownership and exposure to ruminants and pets, consumption of unpasteurized milk, medical history, tick-bites, use of manure in garden, contact with agricultural products such as hay and straw.

Study description

Background summary

Q fever seems to be re-emerging among ruminants and humans in the Netherlands leading to a growing public health concern. This disease, caused by Coxiella burnetii, is a zoonosis with a worldwide distribution that affects both humans and animals. Internationally, the most frequent sources of human Q fever are

domestic ruminants, such as cattle, goats and sheep. Transmission to humans is primarily through the aerosol route. The clinical presentation in humans varies from asymptomatic to severe pneumonia. Chronic infection and reproductive disorders may also develop. Infections in ruminants are mainly subclinical, but abortions and preterm birth of stillborn animals can occur.

Since May/June 2007, the number of human cases has been increasing (2007: 160, 2008: 1000, 2009 up to early June about 900). Since 2005, abortion waves due to Q fever occurred on several dairy goat farms in the same region. A study on the seroprevalence of C. burnetii in the general human population is ongoing. However, the current prevalence of C. burnetii in sheep and goats and in high-risk human populations is unknown. Old data from the 1980's demonstrated a high seroprevalence in farmers and veterinarians. Currently, no evidence-based effective control measures are available. Therefore, a concerted action of human and veterinary experts is taken to identify individual and farm-related risk factors,*high-risk* regions and consider the risk of occupational exposure to C. burnetii in the agriculture sector.

From a public health perspective, the development towards large-scale farming (so called 'megastallen'), also observed among goat farms, raises concern among the public and health professionals about the infection risks of neighbouring communities, for which scientific evidence is lacking. This integrated approach can further elucidate the role of herd size on infection risk in both animals and humans.

Study objective

Overall aim: to determine the extent and risk factors for farm-based and individual acquisition of Coxiella burnetii infections on ruminant farms to improve veterinary, occupational and public health by providing leads for primary (reduce circulation in the ruminant reservoir) and secondary (reduce transmission from infected animals to humans) prevention.

To achieve this, the following objectives are formulated:

1. To determine C. burnetii serostatus in small ruminants (sheep and goats) and livestock farmers (sheep, goats), their adult family members and (preferably young trainee) farm workers.

2. To determine farm-based and individual risk factors for positive serostatus for C.burnetii in small ruminants and humans working or living on livestock farms.

3. To develop laboratory-based tools for source investigation in future outbreaks by creating a baseline database of circulating subtypes of C.burnetii in human (if possible), small ruminants and the farm environment in the

Netherlands.

Study design

A cross-sectional seroprevalence and risk factor study among livestock farmers, adult family members, farm workers and livestock on ruminant farms. A random sample will be drawn from the UBN-database of the Animal Health Service (GD) stratified by ruminant type (goat, sheep, dairy cattle) based on sample size calculations and expected participation (40%).
All eligible farms in the sample will receive a letter and an information leaflet explaining the purpose of the study, the way their data will be used and a response card. All approached farms will be asked to sign a written informed consent before actual enrolment in this study. Individual participants (adults, and youth (12-17 years) will be requested to provide a blood sample, with a maximum of three persons per farm. A self-administered farm-based questionnaire will be obtained to identify risk factors and the farm history, as well as a questionnaire for each individual providing blood to assess individual exposure and risk factors. In a subset of 30 Q-fever positive and 10 Q-fever negative farms, a more indepth analyses of environmental samples will be investigated to study the spread in the farm environment.

Study burden and risks

For this study, data will be collected through farm visits performed by a research assistant. Individual self-administered questionnaires (about 15 minutes) and a blood sample will be obtained (about 10 minutes) from a maximum of three adults per farm by the research assistant, who gave informed consent The visit will take about an hour, dependent on the number of study participants, and to check the completeness of the questionnaires (1 individual questionnaire per study participant, and 1 farm-based questionnaire per farm visited). The farm-based questionnaire will be self-administered by the farmer (about 30 minutes) and checked for completeness.

Contacts

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Scientific
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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)
Elderly (65 years and older)

Inclusion criteria

Working and/ or living at a ruminant farm (with >100 ruminants (sheep, goats or dairy cattle) in the Netherlands (blood samples from a maximum of three persons per farm)

Exclusion criteria

Persons who are unable to give informed consent or do not have a thorough command of the Dutch language will be excluded.
Fully vaccinated during campaign in fall 2008 at the farm-level.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2009
Enrollment:	1550
Type:	Actual

Ethics review

Approved WMO

Date:	04-08-2009
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	NL28401.041.09