Livestock Farming and Neighbouring residents* health: The VGO-study

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The objective is to investigate whether environmental exposure to livestock farm emissions in the Netherlands poses a health risk among neighbouring residents.

Ethical review	Not approved
Status	Will not start
Health condition type	Tissue disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON38591

Source
ToetsingOnline

Brief title
VGO-study

Condition

- Tissue disorders NEC
- Mycoplasmal infectious disorders
- Respiratory disorders NEC

Synonym
Asthma, carriage of resistant-bacteria, COPD, zoonoses

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van Economische Zaken en Ministerie van Volksgezondheid;Welzijn en Sport;en het Longfonds (voorheen Astmafonds).

Intervention

Keyword: livestock farms, Public health, residents health, zoonoses

Outcome measures

Primary outcome

Cross-sectional study (n=3000 (2500 + 500 controls)):

All participants of the cross-sectional study will receive a questionnaire and

a medical evaluation will be conducted on the participants.

The main study parameters:

-Respiratory health effects: pre- and post-bronchodilator lung function, atopic

status (specific serum IgE to common allergens), and respiratory symptoms

(questionnaire).

-Zoonoses: antibodies to (respiratory) zoonotic pathogens and other pathogens

that are potentially associated with livestock farming.

-Resistant microorganisms: nasal MRSA carriage, ESBL-producing bacteria in

faecal samples and Clostridium difficile from faecal samples.

Longitudinal ESBL follow-up study (n= 25 ESBL positive patients and 25

controls):

In total 25 patients who tested positive for ESBL during the cross-sectional

study, will be asked for repeated samples (rectum swab). In total five repeated

samples will be asked with an interval of one month.

The main parameter:

-Carriage of ESBL-producing bateria

Longitudinal panel study (n=100 + 50 controls):

Individuals included in the panel study will measure peak expiratory flow repeatedly over time and keep a symptom diary. Bronchial hyper-responsiveness will be assessed to characterize this subpopulation at one point in time.

The main parameters:

-Peak flow

-Usage of medicines and respiratory symptoms (dairy)

For all these parameters results of the air sampling and GP questionnaire data will be used to study relationships between measured emission and health effects, also taking into account distance to farming in general.

Outbreak study:

An adequate biological sample(s) and short questionnaire regarding among other animal (products) contact or exposure.

Main parameter:

-Antibodies against zoonosis

Secondary outcome

-

Study description

Background summary

There is an ongoing debate regarding environmental health risks of livestock farming in the Netherlands. Emerging outbreaks of zoonotic diseases such as

Q-fever and avian influenza have called attention to various human health risks that may result from building larger and more concentrated types of farms near residential areas, including current farm locations. Residents of many (new) urban areas, located less than a few hundreds meters to a few kilometers from commercial farming activities, may be exposed to harmful infectious and resistant microorganisms, gases, and dust particles containing toxins. So far, little is known about health effects of farm-related exposures to dust and microbial agents among residents.
Between 2009 and 2011, a Dutch study was conducted *Intensieve veehouderij en Gezondheid* (IVG). This multidisciplinary study explored exposure to PM10 (fine dust), microbial agents in PM10 and health effects using General Practitioners (GP) consultation data. In this study, proximity to farms was inversely associated with asthma, COPD, upper respiratory tracts infection and hay fever while proximity of a goat or poultry farm was positively associated with pneumonia. There is little information in literature about health risks for people living near farms, but the available literature suggests several potential community health risks, like zoonoses, and respiratory health effects.

Study objective

The objective is to investigate whether environmental exposure to livestock farm emissions in the Netherlands poses a health risk among neighbouring residents.

Study design

Observational cross-sectional study with a longitudinal follow-up of a subgroup of participants, a longitudinal panel study and a potential outbreak-study.

Study burden and risks

Participants in the cross-sectional study will be asked to visit a research center. The use of temporary research centers sets the maximum travel distance for each participant to 10 km. During the visit to the research center, a standard forced exhalatory spirometric lung function test will be conducted, blood (2 * 10 mL and 1 * 5 mL) will be collected via venapuncture, a nasal swab and a nasal and buccal brush will be taken. Sampling instructions for a faecal sample will be sent to the participant prior to the survey visit. Faecal samples will be taken by the participants at home and sent to the laboratory by mail. The visit (excluding travel time) will take around 45 minutes of time.
For participants who are not able to visit the research center (for instance physical disabled participants), a nurse practitioner will visit them at their home address for the lung function test, blood sampling, nasal swab, and nasal and buccal brush.
In total 25 ESBL positive participants and 25 ESBL negative participants will

be selected from the cross-sectional study and included in the ESBL longitudinal follow-up study. In total five rectal swabs will be asked from the participants with an interval of one month. Rectal swabs will be taken by the participants at home and sent to the laboratory by mail.
For the longitudinal panel study, participants will be asked to register peak expiratory flow at three moments of the day for up to four periods of two weeks, in an overall period of 4 months. At the same time presence and severity of respiratory symptoms, use of medication for respiratory symptoms, and self-reports of odours will be recorded.
In case of a zoonotic outbreak, participants who give consent will be asked to fill out a targeted short questionnaire regarding animal contact and other possible sources of the infection and provide an adequate biological sample(s).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria:
- Resident of the province of Noord-Brabant or the northern area of Limburg covered by the participating GP*s of the GP-network of NIVEL
- Aged between 18 and 70 years
- Living in a rural area
- Giving consent on the screening questionnaire to be contacted for follow-up.
Longitudinal panel study:
- Non-smoker

Exclusion criteria

Exclusion criteria
Cross-sectional study:
Contraindications for spirometry:
Relative contraindications:
- Observed minus Predicted FEV1 is below -1.5L for men and -1.2L for women
- Spirometer induced airway obstruction
- Use of a still active bronchodilator
- Recent exacerbation of asthma or COPD, recent airway infection
- Pregnancy, hypertension, epilepsy
Longitudinal panel study:
Exclusion criteria bronchial hyper-responsiveness (BHR) test:
Absolute contraindications:
- FEV1 < 1.2 L
- Recent (<3 months) severe cardiovascular disease
- Relative contraindications as above

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	3200
Type:	Anticipated

Ethics review

Not approved

Date:	16-08-2013
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	NL45308.041.13