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

Published: 20-01-2014
Last updated: 22-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	General system disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON45022

Source
ToetsingOnline

Brief title
VGO-study

Condition

- General system disorders NEC
- Hepatobiliary neoplasms malignant and unspecified
- Congenital respiratory tract disorders

Synonym
airway microbioom, Asthma, carriage of resistant-bacteria, COPD (Chronic Obstructive Pulmonary Disease), 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 en het Longfonds.

Intervention

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

Outcome measures

Primary outcome

inflammatory responses by peripheral blood cells (in sub-population n = 350)

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 and

Clostridium difficile from faecal samples.

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

controls):

In total 25 participants 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.

Primary study parameter:

-Carriage of ESBL-producing bacteria

MRSA case-control study (n=13 MRSA positive participants and 52 controls):

In total 13 MRSA positive and 52 MRSA negative participants of the

cross-sectional study, will be asked for one repeated sample (neus-swab).

Primary study parameter:

-Carriage of MRSA

Airway microbioom study (n= 100 COPD patients and 200 controls):

Participants will be visited at home three times, a nasal and throat swab will be taken during each visit.

Primary study parameter:

- the composition of nasopharyngeal and oropharyngeal microbiota

COPD panel study:

In total 100 COPD patients will register during three months; twice daily peak-flow, daily dairy and a weekly questionnaire.

Primairy study parameterL

- Daily peak-flow
- Daily respiratory symptoms and medication usage (dairy)

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

Secondary outcome

Cross-sectional study (n=2 500)

-Single nucleotide polymorphisms (SNPs)(EDTA blood tubes) in candidate genes for respiratory and allergic disease. This will enable the evaluation of potential genetic susceptibility and gene-environment interactions at a later stage (additional funding is required).

-DNA methylation (nasal and buccal mucosa cell DNA) in asthma candidate gene

loci will potentially be measured by a pyrosequencing assay (at a later stage;

additional funding is required).

Study description

Background summary

Since several years, there is more attention to health of residents living near livestock farms. Discussions about potential public health risks accelerate due to the Q-fever epidemic and the increasing number of livestock-related antibiotic resistant bacteria (for example MRSA- and ESBL-bacteria). In 2011 a explorative study was conducted to look at the association between GP registered health effects and distance to livestock farms in combination with measured concentration of airborne fine dust and (parts of) bacteria nearby livestock farms (Heederik & Ijzermans 2011). Results were a motivation for a more extensive study to look at exposure of residents living near livestock farms and health risks of this exposure.

Study objective

The generic objective of the study is to explore associations between exposure to livestock farms and potential health effects. This study will focus on 1) respiratory health effects, 2) Livestock associated infections (zoonoses), 3) Carriage of resistant micro-organisms.
Primary Objectives are:

Respiratory health effects
- To study associations between exposure to livestock farm emissions and respiratory effects including symptoms and lung function (spirometry) in a population sample of individuals living at varying distances of livestock farms. In a subsample of individuals with COPD, changes in lung function, respiratory symptoms, and respiratory medication use over time in association with temporal changes in farm exposures will be studied. The composition of nasopharyngeal and oropharyngeal microbiota will be compared between COPD patients and healthy subjects with a low or high density of animal farms around their homes.

Livestock associated infections
- To assess (previous) exposure to several livestock-farming associated pathogens by studying serological responses to these micro-organisms in a population sample of individuals living at varying distances to livestock farms.

Carriage of resistant micro-organisms
- To determine the prevalence of carriage of livestock-associated resistant microorganisms in a population sample of individuals living at varying distances of animal farms.
- To study associations between livestock related exposures to resistant microorganisms and human carriage of these microorganisms in a population sample of individuals living at varying distances of animal farms.

Persistence of ESBL-forming bacteria
The primary objectives are:
- To study the persistence of ESBL-forming bacteria in the general population over a 5-month period.

Persistence of MRSA and the possible association with horse-contact:
- To study the persistence of MRSA in the general population over a 1-2 year period.

Study design

Observational cross-sectional study with longitudinal follow-up studies and a panel study in different subgroups of participants.

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 (total 25 mL) will be collected via venapuncture, a nasal swab and a nasal and buccal brush will be taken. The visit (excluding travel time) will take around 45 minutes of time. Prior to the survey visit, participant will receive a questionnaire and sampling instructions for a faecal sample. Faecal samples will be taken by the participants at home and sent to the laboratory by mail. Completing the questionnaire takas approximately 30 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 125 ESBL positive participants and 250 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 send to the laboratory by mail. Additional, participants will be asked to complete a short questionnaire (2 minutes).

In total 13 MRSA positive and 52 MRSA negative participants will be invited from the cross-sectional study to participate to the MRSA case control study. Participants will be asked to take one nose-swab and one short questionnaire and to send to the laboratory by mail. This will take in total 15 minutes of time.

Participants of the airway microbiome study (100 COPD patients and 200 controls) will be visited three times at their home by a research worker, a nasal and throat swab will be taken during each visit. Participants will fill out a short questionnaire. The home visit takes 10 minutes of time.

Participants of the COPD-panel study will be visited three times. The first visit will takes 45 minutes of time and the second and third visit will take 30 minutes of time. The COPD patients will be asked to measure peak flow twice a day, to complete the diary daily, and to fill out an additional short questionnaire every week, during the study period of 3 months. This will take 10 minutes of time per day.

Contacts

Public
Universiteit Utrecht

yalelaan 2
Utrecht 3584 CM
NL
Scientific
Universiteit Utrecht

yalelaan 2
Utrecht 3584 CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Resident of the province of Noord-Brabant or the northern area of Limburg covered by the participating GP*s (General Practitioner) 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.
Longitudinale ESBL and MRSA follow-up study:
-Participants who tested ESBL-positive during the cross-sectional study. In addition, per each invited ESBL positive participant two participants who tested ESBL-negative will be selected at random from the same research center.
-Participants who tested positive for MRSA during the cross-sectional study. And per individual invited participant, four controls (who tested negative for MRSA) will be invited.
COPD panel study and airway microbiome study:
COPD patient:
- Prior given consent to be contacted for follow-up during the cross-sectional study
- Airflow limitation (post-bronchodilator fixed ratio of FEV1/FVC less than 0.7)
Control subject:
- Prior given consent to be contacted for follow-up during the cross-sectional study
- For each COPD patient, 2 controls will be selected at random from the same research center.

Exclusion criteria

Exclusion criteria
Cross-sectional study:
If a potential subject meets one of the contraindications for spirometry, the subject will be excluded for sub-study: *A. Respiratory effects* (the subject can still participate to other parts of the study).
Absolute contra-indications spirometry
-Heart attack in the last three months
-Chest or abdominal surgery in the past 3 months
-Ascending aortic aneurysm
-Heamopthysis
-A brain, ear or eye surgery in the past 1 month
-Pregnancy (last trimester);Relative contra-indications
-Patient discomfort (diarrhea, vomiting, common cold)

If a potential subject meets one of the contraindications for reversibility test, the subject will be excluded from the reversibility test.
Absolute contra-indications reversibility test:
-Use of medication that can be influenced by salbutanol or can influence the effect of salbutamol
-Pregnancy (second trimester),
-Breastfeeding
-Diabetes
-Hypertension
Relative contra-indication reversibility test:
-Use of salbutamol within 4 hours a prior of the reversibility test
Longitudinal ESBL follow-up
- Having COPD
- Being C. difficile positive;MRSA case-control study:
-participant of the COPD panel study
-Participant of the ESBL longitudinal study;COPD panel study and airway microbiome study:
COPD patient:
- Current smoker
Control subject:
- Current smoker
- Airflow limitation (post-bronchodilator fixed ratio of FEV1/FVC less than 0.7), or reversibility >12%
- Self-reported COPD or asthma

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:	Recruitment stopped
Start date (anticipated):	10-03-2014
Enrollment:	2500

Type:	Actual

Ethics review

Approved WMO Date:	20-01-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	06-03-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	06-10-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-07-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-03-2016
Application type:	Amendment
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	NL45307.041.13