Livestock Farming and Neighbouring Residents* Health: Part 3

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49112

Source
ToetsingOnline

Brief title
VGO-3 study

Condition

- Other condition
- Respiratory tract infections

Synonym
infection of the lungs, pneumonia

Health condition

microbioom

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: NWO (ZonMW: TOP subsidie),ministerie van VWS

Intervention

Keyword: Livestock Farming, microbiome, pneumonia, Residents Health

Outcome measures

Primary outcome

Control subjects, goat farmers (and patients)

• Pathogen detection in nasopharyngeal swab by multiplex PCR of 33 respiratory

pathogens (for details, see 8.3);

• Coxiella burnetii detection in nasopharyngeal swab by PCR;

• Oropharyngeal microbiota composition (16S rRNA sequencing);

• In subpopulation: nasopharyngeal/oropharyngeal virome and metagenome.

• serum response to SARS-CoV-2

Control group

• Pre-bronchodilator lung function;

• Respiratory symptoms (questionnaire).

Goat farmers

• Serology on farm related pathogens including Coxiella burnetii;

• Serology on farm related thermophilic bacteria as markers for

Hypersensitivity Pneumonitis (Extrinsieke Allergische Alveolitis).

Secondary outcome

Control group

• Atopic status, specific serum IgE to a panel of common inhalant allergens

namely: grass, tree, house dust mite, cat and dog;

Goat farmers

• Respiratory symptoms and exposure related to type of farm work

(questionnaire);

• Gut microbioata composition in faecal sample (16S rRNA sequencing);

Study description

Background summary

Exposures which originate from livestock farms, such as dust, (zoonotic) microorganisms, endotoxins, and ammonia are associated with adverse health effects in neighbouring residents. Several distinct signals have been found recently: increased respiratory symptoms and medication use in chronic obstructive pulmonary disease (COPD) patients living near livestock farms, acute airway obstruction associated with elevated ammonia concentrations, and an elevated risk for pneumonia near poultry and goat farms, accompanied by a shift in the respiratory microbiome. The underlying causes have not been unravelled.
We hypothesize that the excess pneumonia risk results from either inhalation of potentially farm-related pathogens, or, alternatively, from other farm-related exposures that lead to changes in the composition and diversity of the upper respiratory tract microbiome and virome leading to excess pneumonia risk through dysbiosis. These hypotheses will be studied in the so-called VGO-3 study. While awaiting the results of the VGO-3 study, 9 of the 12 provinces have stopped issuing building permits for new and existing goat farms.

Study objective

A primary objective of the study is to explore the underlying causes of the excess pneumonia risk in individuals living in the proximity of goat farms. Another objective is to study associations between long-term exposure to livestock farms and respiratory health, namely respiratory symptoms, atopic sensitization, and lung function decline over a six-year follow-up period.

A secondary objective of the study is to to identify potential exposures responsible for a decreased prevalence of asthma and allergy observed in neighboring residents living close to a farm.

Study design

A cross-sectional analysis of the microbiome and virome of the oral and nasal pharynx is performed in three different populations: (1) patients diagnosed with pneumonia, living in an area with a high density of goat farms, (2) a general population sample in a similar area (control group) and (3) employees and owners of goat farms. Potential causative pathogens and shifts in the respiratory microbiome and virome will be studied.

Study burden and risks

Burden: all subjects are requested to fill in a questionnaire and from all subjects a swab from the nasal and the oral pharynx and a blood sample (1 * 10 mL) via venepuncture will be taken. In addition, participants in the control group will perform a standard forced exhalatory spirometric lung function test. From participants in the goat farmers group and a stool sample will be collected. total time control subjects and goat farmers: 55 minutes.
Risks: This is an observational study, involving minimal risks for participants (taking a single nasal and oral swab, a lung function test in 1600 control subjects, and taking a blood sample in a subgroup of 150 participants).
Benefits: The study has no direct benefits for the participants. The study will give relevant insight into the increased risk of pneumonia in areas with a high density of (goat) farms as well as in environmental factors contributing to this increased risk. Finally, the study will also contribute to a better understanding of how (shifts in) the (respiratory) microbiome and virome contribute to development of pneumonia and respiratory health in general.

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

(Patient population: being diagnosed with pneumonia (ICPC-code R81) at GP-office)
Control group: participated in VGO-1-study
Goat farmers: working on a goat farm

Exclusion criteria

Control group: no exclusion criteria. There are contra-indications for performing lung function testing:
- Heart failure including heart attack in the last three months
- Chest or abdominal surgery in the past 3 months
- Ascending aortic aneurysm
- Haemoptysis
- A brain, ear or eye surgery in the past 1 month
- Usage of immunsuppressants/ chemotherapeutics
- Immunodeficiency
- Pregnancy (last trimester)
- Participants discomfort (diarrhea, vomiting, common cold)
Goat farmers: not able to communicate in Dutch

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2020
Enrollment:	1750
Type:	Actual

Ethics review

Approved WMO Date:	12-02-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	06-07-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-03-2021
Application type:	Amendment
Review commission:	METC NedMec

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	NL71068.041.19