Q-Kids

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To estimate the risk of Q fever infection in children and adolescents in various exposure groups, estimate the true regional incidence of Q fever infections in children and adolescents, identify associated risk factors, and assess the impact of Q...

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

Summary

ID

NL-OMON37963

Source
ToetsingOnline

Brief title
Q-Kids

Condition

- Bacterial infectious disorders

Synonym
coxiellosis, Q fever

Research involving
Human

Sponsors and support

Primary sponsor: GGD Zuid Limburg
Source(s) of monetary or material Support: GGD Zuid Limburg

Intervention

Keyword: Children, Health status, Q fever, School performance

Outcome measures

Primary outcome

Q-fever attack rate in children and adolescents following primary contact exposure, regional incidence of Q fever in children and adolescents, risk factors associated with infection, impact of infection on health status and school performance (as measured, for example, by absenteeism rates and school reports)

Secondary outcome

Niet van toepassing

Study description

Background summary

Q fever is a zoonosis caused by Coxiella burnetii. Most cases of Q fever are reported in adults.1 While seroprevalence data in children are limited, they nevertheless show that children and adolescents are frequently exposed to Coxiella burnetii. Yet, little is known about the disease, its course and associated risk factors in this group. Whereas existing literature suggests that Q fever illness in children runs a milder course than in adults, it is likely that the morbidity related to Q fever in children is underestimated as many infections are overlooked or misdiagnosed. While children and teenagers younger than 18 years represent about 17% of the population in South Limburg, less than 10% of all individuals tested for Q fever in the year following the veterinary outbreak were from that age category. Further research is necessary to assess whether this discrepancy was caused by differences in exposure, in immunological response to infection and/or in clinical presentation leading to underdiagnosis due to milder or less specific signs and symptoms in younger patients. Only 14% of all younger patients tested had IgM-antibodies to Coxiella, whereas in adults 26% had evidence of acute or recent infection, suggesting that clinical presentation in children may be an even less reliable predictor of infection and disease than in adults. Missed diagnosis or misdiagnosis in children and adolescents, as in adults, may lead to wrong, delayed, or foregone treatment, with possible serious implications such as late-onset chronic Q fever. While acute infection may affect normal development and school performance in schoolchildren, e.g., through absenteeism or symptoms

related to a post-Q-fever fatigue syndrome similar to that in adults, this relationship has never been studied before. Sequelae following acute Q fever infection may be even more severe in children and adolescents with serious learning difficulties, who may run additional behavioral risks of contracting the infection, and whose ability to communicate subjective symptoms of disease may be compromised by their disability, hampering adequate diagnosis and treatment.

Study objective

To estimate the risk of Q fever infection in children and adolescents in various exposure groups, estimate the true regional incidence of Q fever infections in children and adolescents, identify associated risk factors, and assess the impact of Q fever infection on children*s and adolescents* health and school performance status

Study design

Two retrospective cohort studies

Study burden and risks

Parents/guardian(s) of participating children and adolescents will be asked to complete a questionnaire; participating children and adolescents will be asked to have a small blood sample taken by finger-prick during a single dedicated session at school. The researchers may collect data on health and performance status of participating children and adolescents from various sources, including the school, general practitioners and the youth health department of the Public Health Service South Limburg; participants or parents/guardian/(s) may refuse collection of these data by ticking the appropriate opting-out box on the consent form. Estimated time required to complete the questionnaire is approximately 15 minutes. Drawing blood by finger-prick is a proven method which is minimally invasive and generally well-accepted by children. It carries no risks to participants* health. Incidental confirmed positive results may lead to some degree of psychological distress in the child and/or parents/guardian(s), which, however, may be outweighed by potential benefits (i.e., knowledge about Q-fever status and - in the unlikely event of acute or ongoing Q fever infection - appropriate treatment of the child in question by their GP, or referral to specialist care). Much attention will be given to optimal patient information. Little is known about the incidence, risk factors and potential sequelae of Q fever in children. Most cases of Q fever are reported in adults. While seroprevalence data in children are limited, they nevertheless show that children are frequently exposed to Coxiella burnetii.1 One of the reasons for this seeming contradiction is the marked difference in Q fever*s clinical manifestation between children and adults. Generally speaking, a milder course of disease and less specific symptoms seem to set children

apart from adults with regard to Q fever. In fact, Q fever in children an adults may be considered two different disease entities, with important discrepancies in epidemiology, clinical manifestation, and sequelae, even though the pathophysiological basis for this phenomenon is open to discussion. This means that conclusions drawn from studies in the general population where the bulk of participants so far have been adults cannot simply be generalized to children, as is the case with other subgroups where group-related studies are already underway (e.g., Q fever in pregnant women). In other words, important questions regarding Q fever in children and adolescents cannot be answered from the available body of evidence which is hugely based on adult data. The condition may be grossly underdiagnosed in children, in spite of potentially subtle yet significant effects (such as decline in general health and/or school performance), and children and adolescents at present may inadequately benefit from new insights into the pathophysiology, diagnosis, treatment and prognosis of Q fever. For these reasons, we strongly feel that Q fever studies tailored to the particular subgroup of children and adolescents are not only necessary but also long overdue.

Contacts

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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)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

1. Cohort study: Students at a school for children with serious learning disabilities (Catharinaschool (V)SO voor ZMLK Heerlen, Smidserweg 4, 6419 CP Heerlen, approx. 210 students), aged 4 through 17, who attended the school in 2009; students aged 18 and above will also be included if they attended the school in 2009 and were younger than 18 in that year. Consent is required from both parents/guardians. No teacher will be included in the study.
2. Cohort study: Students at a primary school (Cortemich Brede School Voerendaal, Cortemich 2, 6367 CG Voerendaal, approx. 680 students) and a secondary school (SintermeertenCollege Valkenburgerweg 219, 6419 AT Heerlen, approx. 1400 students), located in the farm*s vicinity, who attended the school in 2009; a small number (n * 7) of children and adolescents (school-aged in 2009) notified to the Public Health Service South Limburg between 2009 and present based on Q-fever positive serology, following testing by a GP or other physician; for any student under the age of 18, consent is required from both parents/guardians/representatives. From the age of 12, consent is required not only from both parents/guardian(s), but also from the participating child or adolescent. No teacher will be included in the study.

Exclusion criteria

Refusal by student and/or parents (or legal representatives) to consent; inability to have blood drawn by fingerstick.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-01-2012
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO

Date:	11-07-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	14-05-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL35684.068.11