Study of susceptibility to bacterial gastroenteritis

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Ethical review	Not approved
Status	Will not start
Health condition type	Gastrointestinal infections
Study type	Observational invasive

Summary

ID

NL-OMON30833

Source
ToetsingOnline

Brief title
Natural experiments: Salmonella & Campylobacter outbreaks

Condition

- Gastrointestinal infections
- Bacterial infectious disorders

Synonym
gastric flu, stomach flu

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Ministerie van Volksgezondheid Welzijn en Sport

Intervention

Keyword: Campylobacter, dose-response, immunological- & genetical susceptibility, Salmonella

Outcome measures

Primary outcome

Serum 1:

serological immune status for Campylobacter or Salmonella

Serum 2 en 3:

serological course of the immunological response to exposure to Campylobacter

or Salmonella

Fecal culture:

excretion of Campylobacter or Salmonella: yes / no

Mouth scraping:

genetic predisposition to severe bacterial gastroenteritis: yes / no

Secondary outcome

not applicable

Study description

Background summary

There is a knowledge gap about the correlation between immune status and the measure of exposure in relation to the risk of gastroenteritis by Campylobacter or Salmonella. This knowledge is crucial to etiologic research and a whole

range of risk-assesments which are being performed in the Netherlands and the rest of the world. These types of research are used to generate recomendations for the government and commodity boards for meat, to decrease the risk of Campylobacter and Salmonella infections.
Animal experiments show the great importance of the role of pathogenicity of a strain and the immune status for Salmonella or Campylobacter at the time of exposure.
Volunteer studies about the dose response relation between illness and exposure to Campylobacter have been performed in the past. Naturally, these studies were performed with adult persons, and with small numbers of people. In the majority of the studies the immune status was unknown, and when the immune status was known and positive at exposure, the outcomes were influences highly by the immune status at exposure.
The dose-response relationship of Campylobacter and Salmonella in humans is in fact nearly unknown. And the variability of this dose-response relationship being subject to the pathogenicity of particular stains is even more unknown.

Study objective

In case of food- or water related outbreaks of bacterial gastroenteritis, the regular research of Municipal Health Services (GGD) and the Food and Consumer Product Safety Authority (VWA) aims at control of the outbreak.
The aim of this project is to extend the regular datacollection of the GGD and VWA, for scientific research regarding:
1. What is the dose-response relationship between exposure to Campylobacter / Salmonella and gastroenteritis? (consumption and degree of contamination of a product, in relation to complaints of gastroenteritis)
2. What is the role of immune status in the suscebtibility of a host for severe infections by Campylobacter / Salmonella?
3. What is the role of certain genetic factors in the susceptibility of a host for severe infections by Campylobacter / Salmonella?

Study design

The regular research of the GGD in case of food- or water related outbreaks of bacterial gastroenteritis will be extended.

Possible participants are: all exposed people (symptomatically as well as asymptomatically)

As soon as possible after exposure, participants fill in a questionnaire of 3 pages, about complaints and consumption of the incriminated foodproduct. And a tube of blood (10 ml), a mouthscraping, and a fecal sample are collected. However, participants who feel that the blood withdrawal is too much a burden, can choose to skip the blood withdrawal.

After 3 weeks the participants will be approached by mail for the second questionnaire about complaints. Participants who have given blood will be approached by phone at 3 weeks and half a year after exposure, to ask whether they are willing to participate in a second and third blood withdrawal.

Study burden and risks

Participation means: 2 x questionnaire, 1 x fecal sample, 1 x mouth scraping, 3 x blood withdrawal (10 ml).

Participants who feel that the blood withdrawal is too much a burden, can choose to skip the blood withdrawal.

Participation and completion of all parts of the study will cost a time investment of one hour per participant.

Contacts

Public
RIVM

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

Inclusion criteria

Exposure to the source of infection (food or water)

Exclusion criteria

People that have not been exposed to the source of infection.
Children younger than one year of age.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	900
Type:	Anticipated

Ethics review

Not approved

Date:	20-08-2007
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	NL17959.041.07