Gastro-enteritis admissions in hospitals: incidence and aetiology

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To determine incidence, aetiology and course of gastroenteritis in case of hospitalisation with gastroenteritis. To gain insight in pathogen-specific duration, seriousness of the disease (including complications), and mortality. To investigate...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational non invasive

Summary

ID

NL-OMON31820

Source
ToetsingOnline

Brief title
GEops: Gastro-enteritis admission surveillance

Condition

- Gastrointestinal motility and defaecation conditions
- Hepatobiliary neoplasms malignant and unspecified

Synonym
gastro-enteritis; stomach flu

Research involving
Human

Sponsors and support

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

Intervention

Keyword: admission, aetiology, gastro-enteritis, pathogens

Outcome measures

Primary outcome

Incidence of gastroenteritis admissions.

Incidence of the following pathogens in patients hospitalised because of gastroenteritis:
Bacteriology (RT-PCR): Salmonella, Shigella, Campylobacter, Yersinia, shigatoxin producing E. coli (STEC), entero-aggregative E. coli (EAggEC), enteropathogenic E. coli (EPEC) and Clostridium difficile
Virology (RT-PCR): rota-, adeno-, astro-, noro- and sapovirus
Parasitology (microscopy and ELISA): Cryptosporidium, Giardia and Dientamoeba fragilis.

The course of illness per pathogen in patients hospitalised because of gastroenteritis, including complications, chronic complaints and costs.

Secondary outcome

The DNA isolated from feces for detection of the pathogens will be used for determining genetic polymorphisms in these patients groups. This study will test genes involved in the specific immune response, in particular Th 1 genes, genes involved in innate immunity, and genes involved in inflammatory responses. The frequency of these polymorphisms will be compared to the frequencies determined in population controls in earlier studies. Furthermore,

patients groups infected with different pathogens will be compared for

frequencies of the polymorphisms.

Study description

Background summary

Systematic and reliable information about incidence and aetiology of gastroenteritis in the Netherlands is limited. Two large scaled epidemiologic studies to gastroenteritis in the general population (Sensor) and the general practitioner population (Nivel) yielded an estimation of 4.5 million episodes of gastroenteritis per year in the Dutch population. In about 220,000 episodes, a general practitioner was consulted. Information on hospital admissions for gastroenteritis is limited to discharge diagnoses, using ICD-9 codes, recorded by Stichting Prismant. These codes are too a-specific for distinction within gastroenteritis. Furthermore, the pathogen causing the gastroenteritis remains unknown in about two-third of the cases. Only a small percentage of patients with gastroenteritis are hospitalised, but the costs of treatment of this group of patients is estimated to be 41 million euros.

Study objective

To determine incidence, aetiology and course of gastroenteritis in case of hospitalisation with gastroenteritis. To gain insight in pathogen-specific duration, seriousness of the disease (including complications), and mortality. To investigate seasonal influences, data collection will comprise one complete year.

Study design

Patient will be invited to the study by a physician/nurse of the ward where the patient was admitted with gastroenteritis.
A control will be recruited on the same ward as the participating patient.

Two feces samples will be collected (besides standard diagnostics of the hospital) and tested for a fixed panel of pathogens.

Patient and control will be asked to fill in a questionnaire before discharge from the hospital. The questionnaire contains questions about (medical) background and possible risk factors.

The physician/nurse is asked to provide some medical data of the patient, using a questionnaire. The results of the standard diagnostics of the patient will be

retrieved.

A second questionnaire will be send to the patient and the control two to three months after discharge from the hospital. This second questionnaire contains questions about complications and chronic complaints.

Patients and or controls mentioning complications or chronic complaints on the second questionnaire will receive a third questionnaire about six months after discharge from the hospital. The third questionnaire again contains questions about complications and chronic complaints.

Study burden and risks

The participants are asked to complete two or three questionnaires. Total length: 15 minutes for the first questionnaire and 5-10 minutes for the second and third questionnaire. Furthermore, two stool samples are asked at the start of the study.

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

A person with complaints of diarrhoea and or vomiting, who is being submitted to the hospital

Exclusion criteria

Not having diarrhoea or vomiting complaints, having had diarrhoea or vomiting complaints in the two weeks before the current episode, being younger than 2 weeks

Study design

Design

Study type:	Observational non 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):	03-05-2008
Enrollment:	1800
Type:	Actual

Ethics review

Approved WMO Date:	15-01-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-11-2008
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	NL20258.041.07