A multicenter study into the diarrhea causing bacteria entero-invasive Escherichia coli (EIEC) and Shigella species

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The invasive bacteria Shigella and entero-invasive E.coli (EIEC) that cause gastro-enteritis, are genetically related and share an infection mechanism. In the Netherlands, Shigellosis is a notifiable disease, while infections with EIEC are not. With...

Ethische beoordeling Status	Niet van toepassing Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21567

Bron

NTR

Verkorte titel

IBESS (Invasive Bacteria E. coli/Shigella Study)

Aandoening

Gastro-enteritis caused by entero-invasive E. coli or Shigella species.

Ondersteuning

Primaire sponsor: Centre for Infectious Disease Research, Diagnostics and Perinatal Screening, National Institute of Public Health and the Environment (RIVM), Bilthoven, The Netherlands ;

Certe Laboratory for Infectious Diseases, Groningen, The Netherlands;
Molecular Unit, Department of Medical Microbiology, University of Groningen, University Medical Center Groningen, Groningen, Netherlands.

Overige ondersteuning: f{ The project is funded by the program for regional projects of the National Centre for Infectious Disease Control

Other funders:

f{ Centre for Infectious Disease Research, Diagnostics and Perinatal Screening, National Institute of Public Health and the Environment, The Netherlands ;

f{ Certe Laboratory for Infectious Diseases, Groningen, The Netherlands;

f{ Molecular Unit, Department of Medical Microbiology, University of Groningen, University Medical Center Groningen, Groningen, Netherlands.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

f{ The effects of the different diagnostic laboratory results on patient bound risk factors, incidence, spread, clinical relevance and economic consequences of infection. The severity of disease will be assessed with the use of the Modified Vesikari Scale (MVS), a validated gastroenteritis severity score for use in outpatient settings.

f{ The effect of certain bacterial strain bound characteristics, both phenotypical and genotypical, on severity and spread of infection.

The effects will be calculated with ordinal regression models, except for the effects of genotypical characteristics. For this, a bioinformatics approach is needed, and a pipeline of bioinformatics tools and a statistic approach will be developed during the study.

Toelichting onderzoek

Achtergrond van het onderzoek

The invasive bacteria Shigella species and entero-invasive E. coli (EIEC) can cause gastroenteritis, and share a similar invasive nature. From results of food related outbreaks, a few in-vitro and in-vivo experiments with a limited number of strains, it appears that the symptoms of infections with Shigella and EIEC are comparable, only EIEC has a higher infection dose. Shigella species and EIEC are not compared with each other in a large prospective study, to our knowledge. Little is known about the incidence and course of infection of EIEC. Infections with Shigella species are notifiable in the Netherlands and infections with EIEC are not, even though differences between them are not clear. Next to this, diagnostics poses a problem, because Shigella species and EIEC are genetically related, they are difficult to distinguish with commonly used molecular diagnostics. Culturing, extensive phenotypic identification and serotyping are needed for identification. These laborintensive and not cost-effective techniques are only performed by reference laboratories.

The IBESS study is started to gain insight into diagnostic algorithms, prevalence, patient and

strain bound risk factors, clinical relevance, spread and impact on public health of infections with EIEC and Shigella species, and how these variables of the two genera relate to each other. A secondary objective is to perform molecular epidemiology to investigate genetic relatedness of EIEC and Shigella species in the Netherlands.

The study was submitted to the MERC of UMC Utrecht. As the study does not require extra procedures for the patients, but uses fecal samples from routine diagnostic procedures, the committee has ruled that the Medical Research Involving Human Subjects Act (WMO) does not apply to the IBESS study and that therefore an official approval of this study by the MERC UMC Utrecht is not required under the WMO.

In IBESS, results of laboratory tests of feces samples and deriving bacterial strains will be combined with epidemiological and clinical data of patients. The fecal samples are submitted to a participating laboratory as part of regular patient diagnostics. The IBESS study group will perform additional laboratory testing and will conduct a single survey for patients by telephone to collect the patient data.

It is estimated that 1100 samples can be included during two year, of which the IBESS group can derive approximately 700 bacterial strains.

Outcomes of the study are:

f{ The effects of the different diagnostic laboratory results on patient bound risk factors, incidence, spread, clinical relevance and economic consequences of infection.

f{ The effect of certain strain bound characteristics, both phenotypically and genotypically, on severity and spread of infection.

f{ Results of molecular epidemiology: the source and relatedness of Shigella and EIEC strains in the Netherlands.

f{ If applicable: recommendations for diagnostics to medical microbiological laboratories in the Netherlands.

f{ If applicable: recommendations about improvements of national guidelines for control of infectious diseases caused by Shigella species or EIEC.

Doel van het onderzoek

The invasive bacteria Shigella and entero-invasive E.coli (EIEC) that cause gastro-enteritis,

are genetically related and share an infection mechanism. In the Netherlands, Shigellosis is a notifiable disease, while infections with EIEC are not. With commonly used molecular diagnostics it is not possible to distinguish the two bacteria. Culturing, phenotypic identification and serotyping, which are all labor-intensive and not cost-effective, are needed for identification. The main objectives of IBESS are to gain insight into prevalence, patient and strain bound risk factors, clinical relevance, spread of disease and impact on public health of infections with EIEC and Shigella species. For evidence-based evaluation of guidelines for Shigellosis and infections with EIEC, the above-mentioned variables of the two genera are compared to each other. Secondary objectives are to optimize diagnostics and to perform molecular epidemiology for investigation of genetic relatedness within EIEC and Shigella species in the Netherlands.

Onderzoeksopzet

After a two year inclusion period, the outcomes can be analyzed.

Onderzoeksproduct en/of interventie

The intervention in the IBESS is a noninvasive single survey assessed by telephone for inquiry of epidemiological and clinical data of the patient. In case of a minor, one of the parents or caretakers will be asked to participate in the survey on behalf of the child.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients of all ages and sex who are 1) suffering from gastro-enteric complaints, and 2) Shigella or EIEC is detected in their feces sample by a IBESS participating medical microbiological laboratory during routine diagnostic procedures.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None, all patients that meet the inclusion criteria can be inclluded.

Onderzoeksopzet

Opzet

Туре:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Controle: N.v.t. / onbekend	

Deelname

NederlandStatus:Werving nog niet gestart(Verwachte) startdatum:01-01-2016Aantal proefpersonen:1100Type:Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

RegisterIDNTR-newNL5448NTR-oldNTR5592Ander registerMERC UMC Utrecht : 15-414/C

Resultaten

Samenvatting resultaten Study is not yet published.