Resistance to antibiotics due to carriage of resistant bacteria in the Netherlands.

Gepubliceerd: 03-08-2010 Laatst bijgewerkt: 19-03-2025

The primary objective of the REBEL study is to collect data needed to design control policies to diminish the spread of ESBL-producing Gram negative bacteria in the Dutch population.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23069

Bron
Nationaal Trial Register

Verkorte titel
REBEL-study

Aandoening

extended-spectrum beta-lactamases
community
risk-factors
molecular epidemiology

breed-spectrum bèta-lactamases
samenleving
risicofactoren
moleculaire epidemiologie

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

According to the first part of the observational study we aim to include 10.000 patients. The main study parameter is the enrollment of 10.000 patients which filled in an informed consent, completed the questionnaire and returned a rectal swab or faecal sample.

According to the second part of the observational study we aim to include 50 patients carrying ESBL-producing strains. The main study parameter of this part is the enrollment of these 50 patients accompanied with the participation of the household members as many as possible.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Resistance to beta-lactam antibiotics (penicillins and cephalosporins) due to extended-spectrum beta-lactamases (ESBLs) is emerging explosively over the world. This resistance is becoming a major public health problem, since ESBL-producing bacteria are found in hospitals, in long term care facilities, in the community, and in food-producing animals. The association of ESBL production with resistance to several other classes of antibiotics is particularly threatening. Data from EARSS (European Antibiotic Resistance Surveillance Study) and from a national survey (ONE study) show that the rapid increase in resistance due to ESBLs is also occurring in The Netherlands. The precise size of the problem, the determinants of the increase in resistance, and the risk factors for the occurrence of ESBL-producing microorganisms in The Netherlands, however, are largely unknown.

An estimate of the size of the problem can be obtained by the prevalence of colonization with ESBL-producing bacteria among patients who visit their general practitioner. Molecular characterization of the ESBL genes, and of the mobile genetic elements and strains carrying these genes, permits to determine whether resistant strains and resistance genes persist in colonized persons, whether spread to household members occurs, and whether related ESBL genes are found in Enterobacteriaceae in food-producing animals.

Objective of the study:

The primary objective of the REBEL study is to collect data needed to design control policies to diminish the spread of ESBL-producing Gram negative bacteria in the Dutch population.

Study design:

An observational study consisting of two parts and a case control study will be performed at the VUmc in collaboration with the AGPN.

Study population:

Observational study part 1: Consecutive patients attending general practices, all patients aged 18 years or older and mental competent.

Observational study part 2: Patients of all ages.

Primary study parameters/outcome of the study:

According to the first part of the observational study we aim to include 10.000 patients. The main study parameter is the enrollment of 10.000 patients which filled in an informed consent, completed the questionnaire and returned a rectal swab or faecal sample.

According to the second part of the observational study we aim to include 50 patients carrying ESBL-producing strains. The main study parameter of this part is the enrollment of these 50 patients accompanied with the participation of the household members as many as possible.

Secundary study parameters/outcome of the study:

After follow-up of the first fifty patients and their household members we will compare these human strains with animal strains but an evident endpoint is not applicable.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Patients will be asked to submit a rectal swab specimen or a faecal sample and to fill in a short questionnaire. No interventions will be done. No risks are associated with participation

and the burden is minimal. In order to give a good representation of carriage on household members we aim to include minors or mental incompetent people as well in part 2 of the observational study. This part of the study will give better results and therefore better implications using also these patient groups.

Doel van het onderzoek

The primary objective of the REBEL study is to collect data needed to design control policies to diminish the spread of ESBL-producing Gram negative bacteria in the Dutch population.

Onderzoeksopzet

Presence or absence of ESBL-producing bacteria.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

De Boelelaan 1117
C.M.J.E. Vandenbroucke-Grauls
Amsterdam
The Netherlands
+31 (0)20 4440488

Wetenschappelijk

De Boelelaan 1117
C.M.J.E. Vandenbroucke-Grauls
Amsterdam
The Netherlands
+31 (0)20 4440488

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

Observational study part 1:

1. Consecutive patients attending general practices;

2. All patients aged 18 years or older.

Observational study part 2:

1. Also patients < 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Observational study part 1: Age younger than 18 years.

Observational study part 2: Mental incompetent patients.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2010
Aantal proefpersonen:	10150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-08-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36316
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2347
NTR-old	NTR2453
CCMO	NL29769.029.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36316

Resultaten

Samenvatting resultaten
N/A