REsistance to BEta-Lactam antibiotics due to extended-spectrum beta-lactamases in the Netherlands

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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.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36316

Source
ToetsingOnline

Brief title
The REBEL-study

Condition

- Other condition

Synonym
carriage with ESBL-producing bacteria; carriage of resistant bacteria

Health condition

dragerschap van ESBL-producerende bacteriën

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: community, extended-spectrum beta-lactamases, molecular epidemiology, risk-factors

Outcome measures

Primary outcome

According to the first part of the observational study we aim to include 2000 to 3000 patients. The main study parameter is the enrollment of 2000 to 3000 patients which filled in an informed consent, completed the questionnaire and returned a rectal swab or faecal sample. Also 550 participants attending the GGD will be asked to participate.

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.

Secondary outcome

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.

Study description

Background summary

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.

Study objective

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 and the GGD Amsterdam.

Study burden and risks

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.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
NL

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

Observational study part 1: consecutive patients attending general practices or belonging to the outpatients population/primary care population, all patients aged 18 years or older and mentally competent.
Observational study part 2 (in combination with the GGD): also patients < 18 years.

Exclusion criteria

Observational study part 1: age younger than 18 years and mentally incompetent; For

approaching patients by postal mail (using the patient file of the GP), GPs will exclude patients who are terminally ill or otherwise not properly approachable. GPs will go through the database of the patient file and sort them out personally.
Observational study part 2: mental incompetent patients.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-08-2010
Enrollment:	2700
Type:	Actual

Ethics review

Approved WMO Date:	25-03-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-01-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-01-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23069
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL29769.029.09
Other	TC = 2453
OMON	NL-OMON23069