

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON23069

### Source

Nationaal Trial Register

### Brief title

REBEL-study

### Health condition

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

breed-spectrum bèta-lactamases  
samenleving  
risicofactoren  
moleculaire epidemiologie

## Sponsors and support

**Primary sponsor:** VU University Medical Center

**Source(s) of monetary or material Support:** ZonMw

## Intervention

## Outcome measures

### Primary outcome

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.

### 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

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.

### Secondary 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.

### **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**

Presence or absence of ESBL-producing bacteria.

### **Intervention**

N/A

## **Contacts**

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## **Eligibility criteria**

### **Inclusion criteria**

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.

## Exclusion criteria

Observational study part 1: Age younger than 18 years.

Observational study part 2: Mental incompetent patients.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-08-2010
Enrollment:	10150
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	03-08-2010
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 36316

Bron: ToetsingOnline

Titel:

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

No registrations found.

### In other registers

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

## Study results

### Summary results

N/A