Antibiotic resistant (ABR) hotspots in the population of Rotterdam: a feasibility study for a future population-based prevalence study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Ancillary infectious topics
Study type	Observational non invasive

Summary

ID

NL-OMON43243

Source
ToetsingOnline

Brief title
ABR population Rotterdam

Condition

- Ancillary infectious topics

Synonym
antibiotic resistance - resistant bacteria

Research involving
Human

Sponsors and support

Primary sponsor: GGD Rotterdam-Rijnmond

Source(s) of monetary or material Support: eigen bijdrage GGD Rotterdam

Intervention

Keyword: antibiotic resistance, population, Rotterdam

Outcome measures

Primary outcome

Prevalence (%) of antibiotic resistant E. coli, S. aureus and K. pneumoniae

strains in a population sample of residents of Rotterdam.

Secondary outcome

Associations between the presence of antibiotic resistance and riskfactors such

as age, sex, travel history, antibiotic use, hospital admissions and workplace.

Study description

Background summary

Although the Netherlands is still considered a country with a low prevalence of multidrug-resistant bacteria, the risk of carbapenemase-producing Enterobacteriaceae and other resistant bacteria have already been reported . International travel and visiting international hospitals have been suggested as important risk factors for the spread of antibiotic resistant bacteria worldwide. Currently, there are no data on the prevalence of carriage of antibiotic resistant strains in population of Rotterdam.

Study objective

The objective of the study is to determine the prevalence of antibiotic resistant E. coli, S. aureus and K. pneumoniae strains in residents of Rotterdam visiting general practitioners in neighborhoods with low socioeconomic status (achterstandswijken).

Our secondary objectives are:

1. To examine potential associations between the presence of antibiotic resistance and risk factors such as antibiotic use, travel history, hospital

admissions and workplace.

2. To assess the feasibility of the study design in this particular setting of Rotterdam in anticipation of a larger population-wide prevalence study in Rotterdam.

Study design

Cross-sectional prevalence study.

This is a pilot study, which next to assessing the primary and secondary outcomes of the study, also determines feasibility in order to develop a more comprehensive surveillance system in the neighborhoods of Rotterdam and develop preventive interventions.

Study burden and risks

After informed consent, nasal and perianal swabs will be collected from the participants along with a short questionnaire. This represents a very mild burden for the participant, but does not produce any benefit because the study is anonymous. However, there is a large potential public health benefit for the community.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Adult (18 years and older)
2. Physically and mentally able to consent and participate (capacitated)
3. Resident of Rotterdam
4. Officially enrolled in the GP practice where enrollment takes place
5. Provides informed consent

Exclusion criteria

All those not eligible according to the inclusion criteria. Additionally, a potential subject who shows inability to communicate with the research team in Dutch or otherwise, will also be excluded from the participation in the study.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-03-2016

Enrollment:	400
Type:	Anticipated

Ethics review

Approved WMO Date:	13-07-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-09-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL56740.078.16