Intestinal colonisation with carbapenemase producing enterobacteriaceae after foreign travel

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Primary Objective: The primary objective of our study was to prospectively study the fecal acquisition of NDM-1 carbapenemases producing Enterobacteriaceae during foreign travel and the persistence rate of acquired NDM-1 carbapenemases producing...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON35813

Source
ToetsingOnline

Brief title
Traveling bacteria

Condition

- Bacterial infectious disorders

Synonym
intestinal bacteria, New Delhi metallo-beta-lactamase

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Carbapenemase producing enterobacteriaceae, Fecal acquisition, Foreign travel, Screening

Outcome measures

Primary outcome

Cumulative incidences will be calculate by dividing the number of travellers diagnosted with a positive resistent Enterobacteriaceae by the number of travellers at risk per continent. The incidence rate of positive resistent Enterobacteriaceae will be calculate by dividing the number of travellers with a positive resistent Enterobacteriaceae by the total travel duration in person days. To determine risk factors for contracting a positive resistent Enterobacteriaceae, a logistic regression model will be used.

Secondary outcome

Not applicable

Study description

Background summary

Bacteria from clinical and non-clinical settings are becoming increasingly resistant to conventional antibiotics. Multidrug-resistant Gram-negative bacteria pose the greatest risk to public health. Not only is the increase in resistance of Gram- negative bacteria faster than in Gram-positive bacteria, but also there are fewer new and developmental antibiotics active against Gram-negative bacteria and drug development programmes seem insufficient to provide therapeutic cover in 10-20 years [Lancet Infect Dis. 2010 September ; 10(9): 597-602].

The increase in resistance of Gram-negative bacteria is mainly due to mobile genes on plasmids that can readily spread through bacterial populations. Unprecedented human air travel and migration allow these bacterial plasmids and clones to be transported rapidly between countries and continents. Much of this

dissemination is undetected, with resistant clones carried in the normal human flora and only becoming evident when they are the source of endogenous infections.

Foreign travel has been demonstrated to be a risk factor for colonization with ESBL-producing Enterobacteriaceae [Antimicrobial Agents and Chemotherapy, Vol 54, Sept. 2010, p. 3564-3568]. Travel to areas with a higher prevalence of strains producing ESBLs was a risk factor for the acquisition of ESBL-producing bacteria. Recently a new type of carbapenem resistance gene, designated blaNDM-1 was found in a patient, repatriated to Sweden after admission to hospital in New Delhi, India.

Enterobacteriaceae with NDM-1 carbapenemases are highly resistant to many antibiotic classes and potentially herald the end of treatment with ß-lactams, fluoroquinolones, and aminoglycosides*the main antibiotic classes for the treatment of Gram-negative infections. Only a few isolates remain sensitive to individual aminoglycosides and aztreonam, perhaps owing to the loss of resistance genes (eg, those encoding aminoglycoside modifying enzymes, 16S rRNA methylases, or blaCMY-4). However, most isolates are only susceptible to colistin and tigecycline.

Study objective

Primary Objective:
The primary objective of our study was to prospectively study the fecal acquisition of NDM-1 carbapenemases producing Enterobacteriaceae during foreign travel and the persistence rate of acquired NDM-1 carbapenemases producing isolates after 6 months. If we know the risk of acquisition during travel we can decide to screen patients for ESBL and NDM carriage when they have travelled and are admitted to the hospital.

Secondary Objective(s):
Our secondary objective was to assess potential travel- associated risk factors for the acquisition of NDM-1 carbapenemases, such as destination, gastroenteritis, and antibiotic use during travel

Study design

Prospective cohort study at the Travel clinic of the department of Infectious Diseases, Leiden University Medical Centre during March and June 2011

Study burden and risks

Not applicable

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

All travellers planning a trip outside Europe are invited to participate in the study, aged 18 years and older.

Exclusion criteria

Duration of travel longer than 3 months
Travelers carrying an ESBL-producing isolate before travel
Companion travellers are excluded in the study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	28-03-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL35942.058.11

Study results

Date completed:	04-10-2012
Actual enrolment:	521