"Sentinel surveillance of imported dengue in returning travelers - trends and virus evolution"

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• to describe the epidemiological trends of dengue infections imported to Europe by returning travelers• to describe the full clinical spectrum of dengue disease imported to Europe by returning travelers• to report the phylogeny, selection pressure...

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

Summary

ID

NL-OMON35589

Source
ToetsingOnline

Brief title
Sentinel surveillance of imported dengue in returning travelers

Condition

- Viral infectious disorders

Synonym
dengue, dengue fever

Research involving
Human

Sponsors and support

Primary sponsor: Umeå University, Dept. Public Health and Clinical Medicine, Epidemiology and Global Health
Source(s) of monetary or material Support: EU FP7

Intervention

Keyword: dengue virus, epidemiology, molecular virology, traveler

Outcome measures

Primary outcome

Only cases with laboratory confirmed dengue infection will be included in the

final data analysis.

number of patients with dengue fever returning from a specific area

number of patients with severe dengue fever according to the revised WHO dengue

case classification and classical case definition

percentage of sequence similarities and differences of dengue virus isolates

Secondary outcome

identification of viral genetic factors associated with severe clinical

manifestions

Study description

Background summary

Dengue is the most rapidly spreading mosquito-borne viral disease in the world.
In the last 50 years, the incidence of dengue has increased 30-fold with
increasing geographic expansion to new countries and, in the present decade,
from urban to rural settings. As a consequence of the expanding geographical
distribution of both the virus and the mosquito vector, increased frequency of
epidemics, and the emergence of dengue hemorrhagic fever in new areas, the WHO
has classified dengue as a major international public health concern. The
reasons for the resurgence are complex, and are likely a combination of
multiple factors, including population growth associated with rapid
uncontrolled urbanization, demographic changes, poor vector control, genetic
changes in circulating or introduced viruses, modulating climatic factors, and
foremost, increased movement of viruses in people among countries and regions

via international travel.
Dengue is caused by four antigenically related but genetically distinct viruses (DENV-1, -2, -3 and -4) belonging to the genus Flavivirus, family Flaviviridae.
A considerable number of studies have revealed that each serotype of DENV is composed of phylogenetically distinct clusters that have been classified into "genotypes" or "subtypes," and each genotype is also composed of phylogenetically distinct "groups" or "clades." The evolution of dengue virus (DENV) is characterized by phylogenetic trees that have a strong temporal structure punctuated by dramatic changes in clade frequency. Studies have suggested that specific viral structures may contribute to increased replication in human target cells and to increased transmission by the mosquito vector. In addition, mutations to the non-structural genes could also play an important role in mediating epidemic transmission and increase disease severity. Phylogenetic and epidemiological analyses suggest that the genotypes and subtypes with greater epidemic potential are now displacing those that have lower epidemiological impact.
Dengue viruses are transmitted by mosquitoes of the genus Aedes, subgenus Stegomyia. The principal vector, Aedes aegypti is now well established in much of the tropical and subtropical world, particularly in urban areas. A second species, Ae. albopictus, is generally considered a less effective vector because, unlike Ae. aegypti, it feeds on many species of vertebrate other than humans, and is less tied to the domestic environment. Nevertheless, the species has been responsible for epidemic transmission in some regions, and in recent years its importance has increased because it has been rapidly expanding its range due to global commerce in used tires and other water-holding items. The introduction and rapidly expanding range of Ae. albopictus in Europe is an iconic example of the growing risk of the globalization of vectors and vector-borne diseases.

Study objective

- to describe the epidemiological trends of dengue infections imported to Europe by returning travelers

- to describe the full clinical spectrum of dengue disease imported to Europe by returning travelers

- to report the phylogeny, selection pressure, genotype replacement and molecular clock analyses of dengue viruses imported to Europe by returning travelers

- to compare the 2009 revised WHO dengue case classification to the classical case definition in a non-endemic population (European travelers) in terms of accuracy, sensitivity, simplicity, and acceptability

- to compare clinical manifestations of dengue in a non-endemic population (European travelers) to a endemic population (Sri Lanka) in terms of application of the 2009 revised WHO dengue case classification

- to compare viral genetic factors and clinical manifestations of dengue in a non-endemic population (travelers) and an endemic population (Sri Lanka)

Study design

prospective observational multi-centre study

Study burden and risks

The only risks of participating in this study are those related to the blood drawn, such as pain at the site of the vein puncture, local hematoma, and the very low risk of infection linked to the vein puncture. There is no direct benefit to the patient for participating in this study. The medical care will be the same whether participating in this study or not.

Contacts

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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

Travelers (all age groups) returning from dengue endemic regions who present with an acute febrile illness suspicious of dengue (onset of fever <=5 days*) within the possible incubation period of a dengue infection (<=21 days).

Exclusion criteria

Travelers presenting with concomitant co-infections (e.g. malaria, rickettsial infections, etc.)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	22-12-2011
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	NL37682.058.11