Travel-Imported Arbovirus infections and mHealth applications for outbreak Risk Assessment: ZIeKA monitor part 2

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

Summary

ID

NL-OMON48637

Source
ToetsingOnline

Brief title
ZIeKA monitor part 2

Condition

- Viral infectious disorders

Synonym
arbovirus infections, mosquito-born infections

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: ZonMw call non-alimentaire zoonose

Intervention

Keyword: emerging arboviruses, mosquito-born infections, public health, travelers

Outcome measures

Primary outcome

The proportion of PCR positive samples containing arboviruses (Dengue,

Chikungunya, Zika, Gele koorts) in travelers.

Secondary outcome

The proportion of positive serology samples of arbovirus (Dengue, Chikungunya,

Zika, Gele koorts) specific IgM en/of IgG in travelers who developed health

complaints during their trip.

Study description

Background summary

In recent years, the observed number and the risk of (re)emerging mosquito-borne infections among human populations have increased substantially. This is attributed to a variety of reasons, including climate change, pathogen adaptation, human behavior modifying the ecosystem of mosquitos, improved diagnostic tests, and increased human worldwide mobility and trade. Until recently such infections were considered of minor public health relevance to populations not residing in tropical areas. This has now changed. The continued importation of vectors and the expansion of a suitable habitat within Europe increases the potential for establishment of mosquito borne disease in new regions. In particular, the invasive mosquitos Aedes Albopictus and Aedes Aegypti, the main vectors for Dengue, Chikungunya, Zika and Yellow Fever present a significant health concern. These mosquitos are now widespread in Southern Europe, where already sustained local transmission of several mosquito-borne diseases, such as Dengue (Madeira, France, Croatia) and Chikungunya (Italy, France) has occurred. As the risk of (re)establishment of vectors upon importation in the Netherlands cannot be ignored.

Study objective

Our primary objective is to enable rapid estimation of the current and future

risks of importation into the Netherlands of major arboviral Aedes-borne diseases (Dengue, Chikunguya, Zika and Yellow Fever viruses). The possibility of (re)establishment of competent vectors for these mosquito-borne infections in the Netherlands in the foreseeable future necessitates timely preparation.

Study design

Observational study nested in the first part of the ZIeKA monitor. Travelers who participate in part 1 of the ZIeKA monitor are eligible. We will ask these travelers to collect blood at home through a finger prick for arbovirus diagnostics.

Study burden and risks

The risk associated with participation will be low. We ask travelers who have a suspected arbovirus infection to collect a bloodsample at home. The materials for the self-collected blood sample will be sent to their home address and can be returned via regular mail.

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

adult travelers, traveling to areas with risk of arbovirus infections.These adult travelers are participants of part one of the ZIeKA monitor.

Exclusion criteria

not willing to collect blood with finger prick

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-11-2018
Enrollment:	348
Type:	Actual

Ethics review

Approved WMO

Date:	03-10-2018

Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	21-06-2019
Application type:	Amendment
Review commission:	METC NedMec

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	NL64191.041.18

Study results

Date completed:	10-06-2021
Results posted:	16-09-2022
Actual enrolment:	239

First publication
16-09-2022