Functional immunity against different malaria life stages in expatriates naturally exposed to P. falciparum.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Protozoal infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON38663

Source
ToetsingOnline

Brief title
IMEX

Condition

- Protozoal infectious disorders

Synonym
malaria immunity

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Europese Unie Marie Curie Fellowship

Intervention

Keyword: Expatriates, Immunity, Plasmodium falciparum

Outcome measures

Primary outcome

A single venous blood sample (32mL) will be taken along with a short questionnaire with questions about malaria exposure and age at first malaria exposure. After anonimisation, peripheral blood mononuclear cell (PBMC these samples will be used to: i) assess functional transmission blocking immunity by standard membrane feeding assay; ii) determine (a reduction in) hepatocyte invasion by sporozoites in the presence of isolated immunoglobulins (IgG), iii) determine the production of interferon-gamma (IFN-*), tumor necrosis factor * (TNF-*) and interleukin-2 (IL-2) in PBMC subpopulations after stimulation with plasmodium infected red blood cells, sporozoites and malaria antigens; iv) determine the antibody profile against a panel of sexual stage, bloodstage and liverstage antigens by protein microarray.

Secondary outcome

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Study description

Background summary

Immunity to malaria develops slowly. Even after repeated exposure sterile immunity that prevents infected mosquito bites from establishing blood-stage infection is rarely observed in endemic populations. Also transmission blocking immunity whereby human antibodies interfere with parasite development in mosquitoes is rarely seen in endemic populations. By contrast, sterile immunity and functional transmission-blocking immunity are commonly observed in adult

populations who are exposed to malaria in experimental infections, during travelling or after exposure to malaria while living in malaria-endemic regions as expatriate. We hypothesize that controlled malaria exposure in adulthood, when the immune system has reached a certain level of maturation, results in a more efficient immunity to different malaria life stages compared to exposure from at an earlier age in life.

Study objective

We aim to test our hypothesis after collecting venous blood samples from adults who were exposed to malaria as expatriate living in malaria-endemic regions. After anonimisation of blood samples, functional immunological assays will be performed in concert with high throughput immune-profiling approaches.

Study design

Cross-sectional

Study burden and risks

The burden and risks of participating in this study are minimal. A short questionnaire without identifying information will be taken, along with a single venous blood sample (32mL) that will be drawn by an experienced medical doctor.

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

Fifty healthy adults who have lived in malaria endemic regions for a minimum of 5 years.

Exclusion criteria

Lived in malaria endemic region for less than 5 years

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2013
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO Date:	14-11-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL46352.091.13