Exposure of human volunteers to live malaria sporozoites under chloroquine prophylaxis

Published: 16-11-2006
Last updated: 09-05-2024

Primary objective (parasitological): To induce protection against malaria by exposure to infectious mosquito bites under chloroquine prophylaxis. Secondary objectives (immunological): 1. To induce an effective immune response against natural malaria...

Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON30242

Source
ToetsingOnline

Brief title
EHMI-8

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
malaria

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Stichting dioraphte

Intervention

Keyword: Falciparum, Malaria, Sporozoite

Outcome measures

Primary outcome

Primary endpoints (parasitological):

1. A significant difference in time of thick smear positivity between exposed and control groups

2. A significant difference in parasitemia as measured by 18S Pf NASBA between exposed and control group

3. A significant difference in kinetics of parasitemia between exposed and control groups as measured by 18S Pf NASBA.

4. A difference in occurrence or height of fever between exposed and control groups.

Secondary outcome

Secondary endpoints (immunological):

1. Significant differences in immune response between exposed and control volunteers

2. Significant differences in the outcome of in vitro functional malaria assays between exposed and control volunteers

3. Significant differences in cellular reactivity against Pf antigens

4. Significant differences in parasite VAR gene expression during infection

5. The identification of immune mechanisms that correlate with protection

6. The identification of potential vaccine candidates that correlate with protection

Exploratory endpoints (pathophysiological):

1. To identify early changes in iron metabolism

2. To identify early plasma changes in endothelial activation markers

3. To identify early changes in flow-mediated vasodilatation (FMD)

Study description

Background summary

Development of a malaria vaccine is hampered by our limited knowlegde of (immunological) correlates of protection. Therefore it is of the utmost importance that factors that contribute to protection are identified, in order to develop a vaccine.

Study objective

Primary objective (parasitological): To induce protection against malaria by exposure to infectious mosquito bites under chloroquine prophylaxis.
Secondary objectives (immunological):
1. To induce an effective immune response against natural malaria parasites in healthy human volunteers by exposure to infectious mosquito bites under chloroquine prophylaxis.
2. To dissect mechanisms of protection and identify correlates of protection.
Exploratory objectives (pathophysiological): To explore the pathophysiology of early malarial infection, with specific attention to:
1. iron metabolism
2. endothelial activation markers
3. endothelial reactivity

Study design

Trial design : unicenter, double blind, randomised
Trial procedure : Volunteers will be exposed to the bites of infectious mosquitoes 3 times (interval 1 month) with live P. falciparum sporozoites under chloroquine prophylaxis. Challenge with infected mosquitoes will be given 28 days after stopping chloroquine prophylaxis.

Intervention

Volunteers will be exposed to infectious mosquitoe bites. They will be treated

with chloroquine, and later with riamet.

Study burden and risks

The main burden to the volunteers that is related to this study is the intensive follow-up period with many visits and venapunctures.

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

Healthy 18-45 y/o

Exclusion criteria

Systemic disorders

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-1007
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Nitrolingual
Generic name:	nitroglycerine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Nivaquine
Generic name:	Chloroquine
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Riamet
Generic name:	artemether/lumefantrine

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	16-11-2006
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-03-2007
Application type:	Amendment
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
EudraCT	EUCTR2006-006074-16-NL
CCMO	NL14967.091.06
Other	nog niet bekend