

A phase I randomised single-blinded single-centre study comparing doses of Plasmodium falciparum chimeric protein 2.9 (PfCP-2.9) recombinant vaccine adjuvanted with Montanide ISA 720 for safety and immunogenicity

Submission date 01/10/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/10/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/04/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RPC 006

Study information

Scientific Title

Study objectives

Primary hypothesis:

To assess the safety and reactogenicity of PfCP-2.9 vaccine in healthy adult volunteers.

Secondary hypothesis:

To assess the immunogenicity of PfCP-2.9 vaccine in healthy adult volunteers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. Independent Ethics Committee, Shanghai Changhai Hospital on the 29th January 2003 (ref: S001)
2. World Health Organization (WHO) research Ethics Research Committee on the 30th April 2003 (ref: RPC 006)

Study design

Randomised single-blind placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Malaria

Interventions

1. Intervention dose group: 20 micrograms PfCP2.9/Montanide ISA 720; administered intramuscularly on Day 0, Day 60 and Day 180
2. Intervention dose group: 50 micrograms PfCP2.9/Montanide ISA 720; administered intramuscularly on Day 0, Day 60 and Day 180
3. Intervention dose group: 100 micrograms PfCP2.9/Montanide ISA 720; administered intramuscularly on Day 0, Day 60 and Day 180
4. Intervention dose group: 200 micrograms PfCP2.9/Montanide ISA 720; administered intramuscularly on Day 0, Day 60 and Day 180
5. Placebo control group: Montanide ISA 720; administered intramuscularly on Day 0, Day 60 and Day 180

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Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Plasmodium falciparum chimeric protein 2.9 (PfCP-2.9) recombinant vaccine, Montanide ISA 720

Primary outcome measure

1. Local and systemic tolerability
2. Reported adverse events

Secondary outcome measures

1. Antibody titres by Enzyme-Linked Immuno-Sorbent Assay (ELISA)
2. Antibody titres by IFA Test (IFAT)
3. Lymphocyte stimulation indices

Overall study start date

11/08/2003

Completion date

18/11/2004

Eligibility

Key inclusion criteria

Healthy adult volunteers ages 18 - 45 years.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Female

Target number of participants

52

Key exclusion criteria

1. History of malaria: persons infected with malaria or with positive markers for antibodies to malaria parasite by Indirect Fluorescent Antibody (IFA) assay
2. History of ever traveling to or residing in a malaria endemic region or malaria exposure within last two years

Date of first enrolment

11/08/2003

Date of final enrolment

18/11/2004

Locations**Countries of recruitment**

China

Switzerland

Study participating centre

Initiative for Vaccine Research

Geneva-27

Switzerland

CH-1211

Sponsor information

Organisation

World Health Organization (WHO) (Switzerland)

Sponsor details

Initiative for Vaccine Research

Special Programme for Research and Training in Tropical Diseases

20 Avenue Appia

Geneva-27

Switzerland

CH-1211

+41 (0)22 791 4760

reedz@who.int

Sponsor type

Research organisation

Website

http://www.who.int/vaccine_research/en/

ROR

<https://ror.org/01f80g185>

Funder(s)**Funder type**

Research organisation

Funder Name

World Health Organization (WHO) (Switzerland) (ref: RPC 006)

Alternative Name(s)

, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

Switzerland

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	09/04/2008		Yes	No