ISRCTN66850051 https://doi.org/10.1186/ISRCTN66850051

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

Registration date
01/10/2007

Last Edited
15/04/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Zarifah Reed

Contact details
Initiative for Vaccine Research
World Health Organization
20 Avenue Appia
Geneva-27
Switzerland
CH-1211
+41 (0)22 791 4760
reedz@who.int

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 Chanhai 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
Rondomised 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

Contact information for Principal Investigator:
Dr Jinhong Hu
Clinical Center of Pharmacology Changhai Hospital
Second Military Medical University
174 Changhai Road
Shanghai 200433
China
Tel: +86 (0)21 25070665
Fax: +86 (0)21 25070665
Email: hjhong2006@gmail.com

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