

Randomised controlled double-blind trial of DNA ME-TRAP/MVA ME-TRAP against malaria infection in Gambians aged 15 to 45

Submission date
01/09/2004

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
05/10/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
10/11/2022

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Vasee Moorthy

Contact details

6290 Montrose Road
Rockville
United States of America
20814

Additional identifiers

Protocol serial number

060147

Study information

Scientific Title

Randomised controlled double-blind trial of DNA ME-TRAP/MVA ME-TRAP against malaria infection in Gambians aged 15 to 45

Acronym

VAC020

Study objectives

A randomised, controlled trial of Deoxyribonucleic Acid (DNA) Multiple Epitope (ME)-Thrombospondin Related Adhesion Protein (TRAP)/Modified Vaccinia virus Ankara (MVA) ME-TRAP in a rural part of Gambia to explore whether this vaccine combination could provide protection against natural *P. falciparum* infection.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Plasmodium falciparum malaria

Interventions

Intervention: Deoxyribonucleic Acid (DNA) Multiple Epitope (ME)-Thrombospondin Related Adhesion Protein (TRAP) malaria vaccination followed by Modified Vaccinia virus Ankara (MVA) ME-TRAP malaria vaccination

Control: Chiron Rabipur rabies vaccine

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Deoxyribonucleic Acid (DNA) Multiple Epitope (ME)-Thrombospondin Related Adhesion Protein (TRAP) malaria vaccination, Modified Vaccinia virus Ankara (MVA) ME-TRAP malaria vaccination and Chiron Rabipur rabies vaccine

Primary outcome(s)

1. Vaccine safety
2. Immunogenicity
3. Time to first *P. falciparum* infection

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/12/2002

Eligibility

Key inclusion criteria

1. 372 Healthy Gambian men aged 15 to 45
2. Resident in villages in the North Bank Division

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

372

Key exclusion criteria

No exclusion criteria provided at time of registration

Date of first enrolment

01/07/2002

Date of final enrolment

01/12/2002

Locations

Countries of recruitment

Gambia

United States of America

Study participating centre

6290 Montrose Road

Rockville

United States of America

20814

Sponsor information

Organisation

London School of Hygiene and Tropical Medicine (UK)

ROR

<https://ror.org/00a0jsq62>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 060147)

Funder Name

Gates' Partnership at London School of Hygiene and Tropical Medicine (UK)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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		01/11/2004		Yes	No