

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	<input type="checkbox"/> Prospectively registered
Registration date 05/10/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/11/2022	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design

Randomised 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**

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 measure

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

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/07/2002

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

Age group

Adult

Sex

Both

Target number of participants

372

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)

Sponsor details

Keppel Street

London

England

United Kingdom

WC1E 7HT

Sponsor type

University/education

ROR

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

Funder(s)

Funder type

Charity

Funder Name

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

Funder Name

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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