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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/10/2004	**Overall study status** Completed	
Last Edited 10/11/2022	**Condition category** Infections and Infestations	

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

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