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

Submission date	Recruitment status	Prospectively registered		
01/09/2004	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
05/10/2004	Completed  Condition category	[X] Results		
Last Edited		[] Individual participant data		
10/11/2022	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

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

#### Study objectives

A randomised, controlled trial of Deoxyribonucleic Acid (DNA) Multiple Epitope (ME)-Thrombospondin Related Adhesion Protein (TRAP)/Modified Vaccinia virus Ankara (MVA) METRAP 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

#### 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