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Safety, immunogenicity and efficacy against febrile malaria of the candidate vaccines FP9 ME-TRAP and MVA ME-TRAP for children in an endemic area

Submission date
13/09/2005

Recruitment status
No longer recruiting

Registration date
14/10/2005

Overall study status
Completed

Last Edited
05/03/2019

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
073597

Study information

Scientific Title
Safety, immunogenicity and efficacy against febrile malaria of the candidate vaccines FP9 ME-TRAP and MVA ME-TRAP for children in an endemic area: a randomised controlled trial

Study objectives
To compare the following outcome measures in children immunised with a control immunisation (rabies vaccine) or FP9:ME-TRAP MVA:ME-TRAP during two three to four month surveillance periods spanning the malaria transmission seasons:
1. Rates of development of febrile malaria and proportions of children with episodes of febrile malaria
2. The incidence of solicited local side-effects at the site of injection and systemic side-effects in the days following immunisation
3. The immediate effector T cell response and long-term memory T cell response after vaccination

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Kenyan Medical Research Institute National Ethical Review Committee, 23/11/2004, ref: SSC Protocol 915
2. Central Office for Research Ethics Committees (COREC), 09/02/2005, ref: 05/Q1604/9

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Febrile malaria

Interventions

This study will evaluate the efficacy of the regime of FP9:ME-TRAP (attenuated Fowlpox virus recombinant for ME-TRAP) followed by MVA:ME-TRAP (modified Vaccinia Ankara recombinant for ME-TRAP) in one to six year old children in Kilifi District, Kenya, during two three to four month surveillance periods spanning the malaria transmission seasons. The trial will be randomised and double blind, using rabies vaccine as control. We will screen 450 children, aiming to recruit 410 children to be randomised in a 1:1 ratio to active or control vaccinations.

Intervention Type
Biological/Vaccine

Phase
Phase II

Primary outcome measure
1. Safety and immunogenicity data will be evaluated by clinical assessments and blood tests
2. Subsequent weekly follow up will allow blood film examinations for all febrile children
3. Rates of development of febrile malaria and proportions of children with episodes of febrile malaria will be compared between groups to determine efficacy

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/02/2005

Completion date
01/11/2006

Eligibility

Key inclusion criteria
1. Aged one to six years old, either sex
2. Resident in the study area

Participant type(s)
Patient

Age group
Child

Lower age limit
1 Years

Upper age limit
6 Years

Sex
Both

Target number of participants
410

Key exclusion criteria
1. Clinically significant skin disorder, allergy, symptomatic immunodeficiency, cardiovascular disease, respiratory disease, endocrine disorder, liver disease, renal disease, gastrointestinal disease, neurological illness, severe malnutrition (mid-upper arm circumference less than 11 cm)
2. History of splenectomy
3. Serum creatinine concentration above the age related normal range in Kilifi
4. Serum alanine aminotransferase (ALT) concentration above the normal range in Kilifi
5. Clinically significant anaemia (i.e. with symptoms of limited exercise capacity, or signs of a high cardiac output state; large volume pulse, heaving cardiac apex beat, resting tachycardia)
6. Blood transfusion within one month of the beginning of the study
7. History of vaccination with previous experimental malaria vaccines
8. Administration of any other vaccine or immunoglobulin within two weeks before vaccination
9. Current participation in another clinical trial, or within 12 weeks of this study
10. Any other finding which in the opinion of the investigators would increase the risk of an adverse outcome from participation in the trial
11. Likelihood of travel away from the study area

Date of first enrolment
01/02/2005

Date of final enrolment
21/03/2005

Locations

Countries of recruitment
Kenya

Study participating centre
Wellcome Trust Laboratories
Kilifi
Kenya
-

Sponsor information

Organisation
University of Oxford (UK)

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Sponsor type
University/education

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ROR
https://ror.org/052gg0110

Funder(s)

Funder type
University/education

Funder Name
London School of Hygiene and Tropical Medicine (UK)

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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	20/10/2006		Yes	No