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A study of MVA85A in healthy infants

Submission date
29/09/2009

Recruitment status
No longer recruiting

Registration date
05/10/2009

Overall study status
Completed

Last Edited
24/03/2016

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

ClinicalTrials.gov (NCT)
NCT00953927

Protocol serial number
C-020-485/TB020; 084785

Study information

Scientific Title

Phase II double-blinded randomised controlled evaluation of MVA85A/AERAS-485 for safety, immunogenicity and prevention of tuberculosis in Bacillus Calmette-Guerin (BCG)-vaccinated, human immunodeficiency virus (HIV)-negative infants

Study objectives
This is a phase II double-blinded randomised controlled evaluation of safety, immunogenicity and efficacy of MVA85A/AERAS-485 in (Bacillus Calmette-Guerin) BCG vaccinated infants without tuberculosis or human immunodeficiency virus (HIV) infection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Cape Town Research Ethics Committee, 17/12/2008, ref: 291/2008
2. Oxford Tropical Research Ethics Committee, 23/07/2008, ref: 37-08
3. Chesapeake Institutional Review Board, 09/07/2008, ref: 598

Primary study design
Interventional

Study design
Phase II double-blinded randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tuberculosis

Interventions
MVA85A/AERAS-485 is a modified vaccinia virus Ankara expressing antigen 85A from Mycobacterium tuberculosis. Half of the subjects will receive a single intradermal vaccination of 1 x 10^8 pfu (plaque forming units) of MVA85A, the other half will receive a Candida skin test antigen (Candin) as a control. Follow up is for 18 - 24 months.

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
MVA85A/AERAS-485

Primary outcome(s)
To evaluate the safety profile of MVA85A/AERAS-485 in BCG-vaccinated, HIV-negative infants. Adverse events are recorded 28 days post-vaccination and serious adverse events are recorded for the entire study period.

Key secondary outcome(s)

1. To evaluate the efficacy of the MVA85A/AERAS-485 vaccine compared to controls in prevention of tuberculosis, assessed at 18 to 24 months post-vaccination
2. To evaluate the immunogenicity of the MVA85A/AERAS-485 vaccine compared to controls as described by ex-vivo Elispot, flow cytometric intracellular cytokine staining or whole blood intracellular cytokine assay
3. To discover correlates of protection from tuberculosis in infants vaccinated with MVA85A /AERAS-485, assessed at 18 to 24 months post-vaccination
4. To evaluate the QuantiFERON conversion rate at final study assessment in MVA85A/AERAS-485 recipients compared to controls in subjects without a diagnosis of tuberculosis during the trial, assessed at 18 to 24 months post-vaccination

Completion date
12/07/2012

Eligibility

Key inclusion criteria
1. Age of 126 through 154 days on the day of randomisation (Study Day 0), either sex
2. Written informed consent obtained from the parents/guardian
3. Weight: by chart greater than 3rd percentile on Study Day 0
4. BCG vaccination within 7 days of birth
5. Generally good health confirmed by medical history and physical examination within 35 days prior to Study Day 0
6. Must have received age-appropriate doses of pneumococcal vaccine as recommended by the South African Department of Health but no injection within 28 day prior to Study Day 0
7. Ability to complete follow-up period of up to 728 days as required by the protocol
8. Completed simultaneous enrolment in the Aeras Vaccine Development Registry protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
126 Days

Upper age limit
154 Days

Sex
All

Key exclusion criteria
1. Acute illness on Study Day 0
2. Fever greater than or equal to 37.5°C on Study Day 0
3. Evidence of significant active infection on Study Day 0

4. Received a EPI immunisation within 28 days prior to Study Day 0
5. Historical or virological evidence of individual or maternal human immunodeficiency virus (HIV-1) infection
6. History of allergic disease or reactions likely to be exacerbated by any component of the study vaccine
7. Previous medical history, or evidence, of an intercurrent illness that may compromise the safety of the infant in the study
8. Evidence of chronic hepatitis from any cause
9. History or evidence of any systemic disease on physical examination or any acute, chronic or intercurrent illness that, in the opinion of the investigator, may interfere with the evaluation of the safety or immunogenicity of the vaccine
10. History of or known tuberculosis or treatment for tuberculosis
11. Shared residence since birth with an individual with tuberculosis or on anti-tuberculosis treatment

Date of first enrolment
13/07/2009

Date of final enrolment
12/07/2012

Locations

Countries of recruitment
South Africa

Study participating centre
University of Cape Town
Cape Town
South Africa
7925

Sponsor information

Organisation
Aeras Global TB Vaccine Foundation (USA)

ROR
https://ror.org/015facm29

Funder(s)

Funder type

Charity

Funder Name
Wellcome Trust - Strategic Award (ref: 084785)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Aeras Global Tuberculosis Vaccine Foundation

Alternative Name(s)
Aeras Global TB Vaccine Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United States of America

Results and Publications

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?
Basic results	See	12/12/2013		No	No