ISRCTN67270384 https://doi.org/10.1186/ISRCTN67270384

Therapeutic vaccination for chronic hepatitis B virus infection in Africa

Submission date 23/11/2005	**Recruitment status** No longer recruiting
Registration date 23/11/2005	**Overall study status** Completed
Last Edited 06/02/2015	**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
060288

Study information

Scientific Title
Therapeutic vaccination for chronic hepatitis B virus infection in Africa

Acronym
HBSMVA

Study objectives
Chronic Hepatitis B Virus (HBV) infection, therapeutic vaccines, Deoxyribonucleic Acid (DNA) vaccine, recombinant modified vaccinia virus Ankara vaccine.

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
Hepatitis B virus

Interventions
This trial will take place in five parts:
1. An open label study in five healthy volunteers, of modified vaccinia virus Ankara (MVA.HBs) (a novel vaccine for HBV), then an open label non-randomised study in healthy volunteers of Deoxyribonucleic Acid vaccine (DNA.HBs) (another novel vaccine for HBV).
2. A study in 32 male e antigen negative chronic carriers of HBV - four way randomisation:
2.1. Lamivudine 100 mg orally (po) daily for 14 weeks
2.2. DNA.HBs 1 mg twice followed by MVA.HBs twice
2.3. Both lamivudine and DNA and MVA vaccinations
2.4. Rabies vaccine three times as a control
3. A study in 16 male e antigen positive chronic carriers of HBV - two way randomisation:
3.1. DNA.HBs 1 mg twice followed by MVA.HBs twice

3.2. Both lamivudine and DNA and MVA vaccinations
4. A non-randomised study in 12 e antigen negative chronic carriers of DNA.HBs 2 mg twice followed by 1.5 x 10^8 of MVA.HBs once.
5. A non-randomised study in 12 e antigen positive chronic carriers of Lamivudine 100 mg daily and DNA.HBs 2 mg twice followed by 1.5 x 10^8 of MVA.HBs once.

Intervention Type
Biological/Vaccine

Primary outcome measure
1. Local tolerogenicity
2. Adverse events
3. Cellular immune responses to overlapping peptides of Hepatitis B surface protein
4. HBV serology
5. Anti-HBs levels, surface antigen
6. 'e' antigen
7. HBV viral load

Secondary outcome measures
No secondary outcome measures

Overall study start date
28/01/2002

Completion date
31/10/2004

Eligibility

Key inclusion criteria
1. Chronic HBV infection
2. Male, 15 to 25 years
3. No evidence of liver inflammation or liver dysfunction

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
77

Key exclusion criteria
1. Egg allergy
2. Serious disorder of any body system

Date of first enrolment
28/01/2002

Date of final enrolment
10/01/2004

Locations

Countries of recruitment
Gambia

Ireland

Study participating centre
International Health and Tropical Medicine
Dublin
Ireland
2

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
University Offices
Wellington Square
Oxford
England
United Kingdom
OX1 2JD
+44 (0)1865 270143
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Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

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	15/02/2011		Yes	No