

Therapeutic vaccination for chronic hepatitis B virus infection in Africa

Submission date 23/11/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/11/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/02/2015	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 1.5×10^8 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 1.5×10^8 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

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Sponsor information

Organisation

University of Oxford (UK)

Sponsor details

University Offices

Wellington Square

Oxford

England

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OX1 2JD

+44 (0)1865 270143

research.services@admin.ox.ac.uk

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