ISRCTN71271385 https://doi.org/10.1186/ISRCTN71271385

A randomised trial of hepatitis B booster vaccination at the age of 13 to 15 years following infant vaccination to assess efficacy against hepatitis B infection and acute hepatitis

Submission date
21/09/2000

Recruitment status
No longer recruiting

Registration date
21/09/2000

Overall study status
Completed

Last Edited
02/07/2009

Condition category
Infections and Infestations

[X] 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

Protocol serial number
G0000531

Study information

Scientific Title

Acronym
GHABS

Study objectives
Added as of 23/04/2007:
A booster dose of Hepatitis B Virus (HBV) vaccine 15 years after infant vaccination will increase the magnitude and duration of immune responses (measured two and 52 weeks after the boost).

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
Hepatitis B Virus

Interventions
Added as of 23/04/2007:
Booster dose HBV vaccine

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Added as of 23/04/2007:
Anti-HBs titers after one year.

Key secondary outcome(s))
Added as of 23/04/2007:
Proportion without anamnestic response following boosting.

Completion date
31/12/2005

Eligibility

Key inclusion criteria

Added as of 23/04/2007:
1. ID and vaccination data matched with Gambia Hepatitis Intervention Study (GHIS) database
2. Born between 1/7/1988 and 31/12/1989
3. Living in selected Health Centre (HC) catchment area's
4. Informed consent participant and parent/guardian

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
Added as of 23/04/2007:
1. No complete informed consent
2. No match found
3. Not fully vaccinated in infancy
4. Not in age range

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
United Kingdom

England

Gambia

Study participating centre
London School of Hygiene and Tropical Medicine
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	15/08/2007		Yes	No