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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Added as of 23/04/2007:
Anti-HBs titers after one year.

Secondary outcome measures
Added as of 23/04/2007:
Proportion without anamnestic response following boosting.

Overall study start date
01/01/2004

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

Age group
Child

Sex
Both

Target number of participants
Added as of 23/04/2007: 500

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
England

Gambia

United Kingdom

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

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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	15/08/2007		Yes	No