

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

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| Submission date 21/09/2000 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 21/09/2000 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 02/07/2009 | Condition category Infections and Infestations | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

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London

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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 |