The persistence of vaccine-induced HBsAg-specific antibodies and immune memory in adults after complete primary vaccination with the GlaxoSmithKline (GSK) hexavalent Infanrix vaccine at infancy (HEP-IMMUNE)

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000001160

Study ID

1000001160

DARWIN EU® study

No

Study countries

Belgium

Study description

In this study, long-term persistence of cellular and humoral immunity against hepatitis B is investigated in students (around 20 YOA) vaccinated with Infanrix-Hexa during infancy. In study participants with HBsAg-specific antibody level titers < 10 mIU/mL, the immune response to a booster vaccination with Engerix-B is explored.

Study status

Ongoing

Research institutions and networks

Institutions

University of Antwerp

Contact details

Study institution contact

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Primary lead investigator

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Study timelines

Date when funding contract was signed
Actual: 23/06/2026

Study start date
Actual: 29/09/2026

Date of final study report
Planned: 31/12/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

This study was supported as an Investigator-Sponsored Study (ISS) within the Supported Studies Programme of GSK (internal trial identifier IIS 24004/308887).

Study protocol

HEP-IMMUNE_protocol_Final_V1.pdf (472.81 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

Anti-HBs titers are measured in all eligible participants. Cellular immunity is assessed in a subset with anti-HBs titers ≥ 10 mIU/mL. Participants with titers <

10 mIU/mL receive one Engerix-B booster, followed by assessment of humoral and cellular immunity for up to 1 month after vaccination.

Main study objective:

1. To assess the persistence of immunity to hepatitis B in terms of seroprotection rate (refer to below for a definition) in adult subjects vaccinated with three or four doses of Infanrix hexa during infancy.

2. To assess the persistence of immunity to hepatitis B in terms of seroprotection rate, percentage of subjects with an anamnestic response in response to an Engerix-B challenge dose in adult subjects vaccinated with three or four doses of Infanrix hexa during infancy who have an anti-HBs concentration < 10 mIU/mL at the start of the study.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

INFANRIX HEXA

ENGERIX B

Medical condition to be studied

Hepatitis B

Population studied

Short description of the study population

Healthy adult volunteers are recruited from a population of students from the University of Antwerp who require an evaluation of their seroprotection against hepatitis B at the occupational health services. Participants can only be enrolled if they received the Infanrix-Hexa vaccination schedule as per the recommendations in the Summary of Product Characteristics, and did not receive any other vaccine targeting hepatitis B.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

250

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency

but are no longer maintained.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No