Comparison of different new and conventional Hepatitis B vaccins in non-responders after 1 standard Hepatitis B vaccination series with Engerix-20 or HBVAXPRO-10, in order to mount a protective response against hepatitis B.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21963

Source
NTR

Brief title
RESPONSE (Dutch: RESPONS)

Health condition

Non-response (anti-HBsAg < 10 IU/l) after a standard Hepatitis B vaccination series (month 0, 1 and 6) with conventional Hepatitis B vaccins (Engerix-20 and HBVAXPRO-10)

Keywords: Hepatitis B vaccine, non-responder, Twinrix, Fendrix

Sponsors and support

Primary sponsor: National Institute for Public Health and the Environment- Leiden University Medical Center- Pharmaceutical companies producing the investigated vaccines
Source(s) of monetary or material Support: see SPONSORS. Pharmaceutical sponsors will not be involved in design of the trial nor data generation and analysis.

Intervention

Outcome measures

Primary outcome

1. Superiority of one of the investigated vaccins;

2. Induced response (dichotomous seroprotection, and hight of the anti-HBsAg) to the investigated vaccins.

Secondary outcome

Adverse events following the investigated vaccins.

Study description

Background summary

Comparison of different new and conventional Hepatitis B vaccins in non-responders after 1 standard Hepatitis B vaccination series with Engerix-20 or HBVAXPRO-10, in order to mount a protective response against hepatitis B.

Study objective

New Hepatitis B vaccins induce a higher anti-HBsAg titer after a standard Hepatitis B series (month 0, 1 and 6) in non-responders (anti-HBsAg <10 IU/l).

Study design

Expected time of inclusion is one year.

Time points of interventions are:

1. Blooddrawing: Months 0, 1, 2 and 3;

2. Vaccination: Months 0, 1 and 2.

Intervention

Hepatitis B vaccination (month 0, 1 and 2) with:

1. Control (Engerix-20 of HBVAXPRO-10);

2. Twinrix;

3. Fendrix;

4. HBVAXPRO-40.

Contacts

Public
RadboudUMC
S. Raven
[default]
The Netherlands
0306086086
Scientific
RadboudUMC
S. Raven
[default]
The Netherlands
0306086086

Eligibility criteria

Inclusion criteria

1. Age 18-80;

2. Anti-HBsAg < 10 IU/l after 3 intramuscular Hepatitis B vaccinations (months 0, 1 and 6) with Engerix-20 of HBVAXPRO-10;

3. Informed consent.

Exclusion criteria

1. < or > 3 Hepatitis B vaccinations;

2. First series of Hepatitis B vaccination with > 1 recombinant Hepatitis B vaccin;

3. Pregnancy;

4. Immunocompromised due to underlying disease of immunosuppresive medication;

5. HBsAg and/or anti-HBcore positive.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2012
Enrollment:	480
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
Data sharing for the RESPONS trial, at publication of related articles, data will be made available to the public. Owing to the privacy and intellectual
property rights legislation, published data will in principle be anonymised/deidentified participant data, including the metadata and documentation necessary for the discovery and correct interpretation of the data. This contributes to the FAIRness of the project data. Data will
be made available via Radboud University’s RIS interface to the public in the CoreTrustSeal certified DANS EASY archive.
The DANS EASY archive is based on Dublin Core metadata and includes the assignment of a persistent identifier (DOI) to the data. See: https://doi.org/10.17026/dans-xf4-c9mh

Data will be available for the long term, at least for the required 10 years set by the Radboud

University Research Data Management policy. Data will be made available via a Restricted Access licence (automated access on request via DANS EASY, by signing a data use agreement to guarantee the correct reuse of the data).

Ethics review

Positive opinion

Date:	22-11-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3011
NTR-old	NTR3159
Other	METC LUMC : P12.130
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Data generated by this trial will be published in a scientific journal.
Raven SFH, Hoebe CJPA, Vossen ACTM et al.Serological response to three alternative series of hepatitis B revaccination (Fendrix, Twinrix, and HBVaxPro-40) in healthy non-responders: a multicentre, open-label, randomised, controlled, superiority trial. Lancet Infect Dis. 2019; (published online Oct 16)
https://doi.org/10.1016/S1473-3099(19)30417-7