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.

Gepubliceerd: 22-11-2011 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21963

Bron
NTR

Verkorte titel
RESPONSE (Dutch: RESPONS)

Aandoening

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

Ondersteuning

Primaire sponsor: National Institute for Public Health and the Environment- Leiden University Medical Center- Pharmaceutical companies producing the investigated vaccines

Overige ondersteuning: see SPONSORS. Pharmaceutical sponsors will not be involved in design of the trial nor data generation and analysis.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

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

2. Twinrix;

3. Fendrix;

4. HBVAXPRO-40.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2012
Aantal proefpersonen:	480
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
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).

Ethische beoordeling

Positief advies

Datum:	22-11-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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