Immunogenicity and safety of HBAI20 Hepatitis B vaccine in non-responders

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In the Phase 2 clinical study, the efficacy of the vaccine in non-responders and the safety of the vaccine will be studied.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON47410

Source
ToetsingOnline

Brief title
Phase 2 HBAI20 Hepatitis B vaccine in non-responders

Condition

- Viral infectious disorders

Synonym
non-responsiveness to hepatitis B

Research involving
Human

Sponsors and support

Primary sponsor: CyTuVax BV
Source(s) of monetary or material Support: bedrijf (CyTuVax)

Intervention

Keyword: adjuvant, hepatitis B vaccination, non-responders

Outcome measures

Primary outcome

The primary study parameter is the efficacy of the HBAI20 vaccination for non-responders. To this end, the immunogenicity of the HBAI20 vaccine will be measured by median antibody titre, GMT, GMT gain and seroprotection. Seroprotection is defined as a fourfold increase in titer or a conversion of seronegative to a virus antibody titre of * 10 mIU/ml.

Secondary outcome

The secondary study parameter is the safety of the HBAI20 vaccine, in which the number and intensity of local and systemic side effects is investigated.

Study description

Background summary

Worldwide people suffer from infection with hepatitis B virus (HBV). There are prophylactic vaccines against HBV available that in most cases provide adequate protection. However a small group (5-7% of the population) reacts not or not sufficiently, these are so-called non-responders. For persons who are likely to come into contact with infected blood (healthcare, care-workers, teachers, police, firefighters and soldiers), CyTuVax has developed a new adjuvant (AI20) to be mixed with the standard hepatitis B vaccine for an effective vaccination against Hepatitis B. The HBAI20 vaccine adjuvant consists of depot-bound rhuIL2 adjuvant (InterLeukin 2) aggregates for the slow release of IL-2 nano-aggregates.

In a previous Phase 1 study it has been shown that the vaccine is safe (side effects between the group of subjects who were vaccinated with the HBAI20 vaccine were similar to the group of subjects who were vaccinated with the standard Hepatitis B vaccine. Furthermore, it was shown that the group non-responders who have been vaccinated with HBAI20 vaccine, 90% had become responders after 3 vaccinations with the HBAI20 vaccine and had developed a protective titer against Hepatitis B.

Study objective

In the Phase 2 clinical study, the efficacy of the vaccine in non-responders and the safety of the vaccine will be studied.

Study design

The current study is a multi-centre, double-blinded, randomized and controlled trial.
The study will be conducted at MUMC+, Maastricht, Ziekenhuis Oost Limburg, Genk and Antwerp University, Antwerp.
The duration of the study is 5 months from the start (V0) until the end (V4) for each subject. The expected total duration of the study is 2 years from the beginning of enrolment to the last visit of the last subject.

Study subjects are healthy subjects that are non-responders for the Hepatitis B vaccine presenting an anti HBsAg antibody titer *10mIU/ml. Subjects who have completed at least 1 vaccination series consisting of 3 or more Hepatitis B vaccinations will be enrolled for participation in groups 1 or 2 after randomization. All the Hepatitis B vaccinations need to be documented for the subjects to be enrolled in the study.
132 to 140 Hepatitis B vaccine non-responders are randomized into *Group 1* (33 to 35 subjects) and *Group 2* (99 to 105 subjects). Hepatitis B non-responders that have received only 3 vaccinations should constitute at least 40% of the total number of subjects in each group.
Group 1 subjects will receive the HBVaxPro-10µg and serve as control group.
Group 2 subjects will receive the HBAI20 vaccine.

Intervention

The subjects are vaccinated three times, in M0, M1 and M2.

Study burden and risks

The study participants will come to the hospital for 5 visits and will be vaccinated 3 times.
From the Phase 1 study it was found that the risk profile of HBAI20 is similar to the risk profile of a standard Hepatitis B vaccination.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In good health as determined by the outcome of medical history, physical examination screening/baseline labs and clinical judgment of the clinical investigator
Age 18 to 59 years, inclusive at the time of enrollment
Willing and able to adhere to the study regimen
Having a signed informed consent form
Documented non-responders: Subjects with documented one or two cycles of Hepatitis B vaccination (total of 3 or more vaccinations) and titer analysis that show that they have not developed the Hepatitis B antibody titer recommended after standard vaccination: anti-HBsAg antibody titer superior to 10mIU/ml

Exclusion criteria

Any infectious disease at the time of screening and/or enrollment
Positive HIV, Hepatitis B virus or Hepatitis C virus serology
Known or suspected immune deficiency
Known or suspected disease that influences the immune system including chronic allergies that require frequent anti-allergy medication, cancer and transplantation recipients

Known or suspected allergy to any of the vaccine components: see IB, IMPD
Dialysis patient
History of unusual or severe reactions to any previous vaccination
History of any neurologic disorder, including epilepsy and autism
Use of medication that influences the immune system (immune suppressive treatment or daily use of corticosteroids)
Any vaccination within 3 months before screening
Blood donation within 1 month before screening
Administration of plasma (incl. immunoglobulins) or blood products within 12 months before screening
Participation in another clinical trial within 3 months before screening
Abnormal pre-treatment laboratory parameters which are clinically relevant according to the investigator
Bleeding disorders, or use of medication for bleeding disorders, and use of anti-coagulants
Female subjects planning to become pregnant or breastfeeding babies until visit 4
Females: positive urine pregnancy test at screening date
Excessive alcohol or controlled drug use - More than 2 alcohol measures per day (one alcohol measure is a beer (250ml) or one glass of wine (125ml) or one strong measure (35ml) or one port/sherry (75ml)). Regular use of controlled drugs
Any Hepatitis B vaccination in the last 6 months

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-03-2017
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	HBAI20 for non-responders
Product type:	Medicine
Brand name:	HBVaxPro10

Ethics review

Approved WMO Date:	03-11-2016
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-09-2017
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	03-05-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2016-002720-91-NL
ClinicalTrials.gov	NCT03415672
CCMO	NL58391.000.16

Study results

Date completed: 09-01-2019

Actual enrolment: 59

Summary results
Trial is onging in other countries