

# Open randomised study for evaluation of an active hepatitis B vaccination (HBVAXPRO) in combination with a passive immunisation with hepatitis B immunoglobulins (Hepatect) for subjects who did not show any or an adequate reaction to a previous sole active hepatitis B immunisation

<b>Submission date</b> 19/08/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 09/10/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/04/2020	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Hans Ludger Tillmann

**Contact details**  
University Leipzig  
Medical clinic II  
Philipp-Rosenthal-Str. 27  
Leipzig  
Germany  
04103  
+49 (0)341 971 2226  
[Hans.Tillmann@medizin.uni-leipzig.de](mailto:Hans.Tillmann@medizin.uni-leipzig.de)

## Additional identifiers

## Clinical Trials Information System (CTIS)

2007-001744-53

### Protocol serial number

EudraCT-Nr.: 2007-001744-53

## Study information

### Scientific Title

Open randomised study for evaluation of an active hepatitis B vaccination (HBVAXPRO) in combination with a passive immunisation with hepatitis B immunoglobulins (Hepatect) for subjects who did not show any or an adequate reaction to a previous sole active hepatitis B immunisation

### Acronym

PAI-Study

### Study objectives

Is there a better response to active hepatitis B immunisation with the parallel administration of passive antibodies?

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval received from the Ethics Committee of University Leipzig on the 25th April 2008.

### Study design

Prospective, two-armed, open, randomised, mono-centre, phase IIb trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Hepatitis B immunisation

### Interventions

One arm receives active intramuscular (i.m.) vaccination with 10 µg HBVAXPRO™ on weeks 0, 2, 4, 16 and 18. One arm receives active i.m. vaccination with 10 µg HBVAXPRO™ on weeks 0, 2, 4, 16 and 18, plus Hepatect® prior to the week 0, 4, and 16 active vaccination. Duration of follow-up is 6 months for both arms.

### Intervention Type

Drug

### Phase

Phase II/III

**Drug/device/biological/vaccine name(s)**

Hepatitis B vaccination (HBVAXPRO), hepatitis B immunoglobulins (Hepatect)

**Primary outcome(s)**

The result of the vaccination strategy, defined as the achievement of the protective anti-HBs antibody titre (PAT) greater than 100 IU/ml during the treatment period (that is including week 22).

**Key secondary outcome(s)**

1. Time from start of treatment to achievement of the protective anti-HBs antibody titre (PST)
2. Amount of anti-HBs antibody titre (UI/ml) on week 22
3. Adverse and serious adverse events
4. Anti-HBs antibody titre during treatment (week 0 - 22) and during the 6 month follow-up

**Completion date**

01/02/2010

## **Eligibility**

**Key inclusion criteria**

1. No adequate response to a previous triple sole active hepatitis B vaccination (anti-HBs titre less than 100 IU/ml)
2. Written informed consent for participation in the study
3. Aged 18 to 65 years, either sex

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

8

**Key exclusion criteria**

1. Hepatitis B surface antigen (HBsAg) positive
2. Anti-hepatitis C virus (Anti-HCV) positive
3. Anti-human immunodeficiency virus (Anti-HIV) positive
4. Any serious or active physical or psychological disease which has an impact on the treatment

option or the compliance of the subject by estimation of investigator

5. Known or obvious pre-existing liver disease (e.g., M. Wilson, haemochromatosis, autoimmune hepatitis, hepatitis C). These diseases are clinically relevant renal, cardiac, pulmonary, vascular or metabolic (disease of thyroid, adrenal disease) diseases, an immune compromised status or malignant diseases

6. Intake of hepatotoxic agents (e.g. aminoglycoside, amphotericin B, vancomycin, cidofovir, foscarnet, cisplatin, pentamidine, tacrolimus, cyclosporin), or a foreseeable necessity or intention for taking these therapeutics within the last two months prior to screening or at inclusion

7. Intake of nephrotoxic agents (e.g. anabolic steroids, ketokonazole, itraconazole, isoniazid, rifampicin, rifabutin, statins), or a foreseeable necessity or intention for taking of these therapeutics within the last two months prior to screening or at inclusion

8. Treatment with immunoglobulins, interferon or other immunologic or cytokine-based therapy concepts with possible impact on a hepatitis B infection, or a foreseeable necessity or intention for taking these therapeutics within the last six months prior to screening or at inclusion

9. Treatment with steroids, immunosuppressives or chemotherapeutic agents, or a foreseeable necessity or intention for taking these therapeutics within the last two months prior to screening or at inclusion

10. Subjects with known thrombophilic disease and/or previous thromboembolic events in the anamnesis

11. Organ or bone marrow engrafted subjects

12. Concomitant participation in other clinical trials or treatment with another investigational drug within the last 2 months prior to screening

13. Planned vaccination outside the vaccination for the trial during the whole study time (e.g. vaccination of influenza)

14. Ongoing alcohol or drug abuse which has an impact on the compliance of the subject, the result of the vaccination during the whole study time or the evaluation of adverse events

15. Allergic reaction to vaccinations or immunoglobulins in anamnesis

16. Women during pregnancy and lactation

17. Women with child bearing potential (less than 2 years after the last menstruation) without effective contraception (implants, injections, oral contraception, intrauterine devices - spirals etc., partner with vasectomy) during the trial (subjects who takes a hormonal method of contraception will be informed about possible effects of the study medication)

**Date of first enrolment**

01/08/2008

**Date of final enrolment**

01/02/2010

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**

University Leipzig  
Leipzig  
Germany  
04103

## Sponsor information

### Organisation

University of Leipzig (Germany)

### ROR

<https://ror.org/03s7gtk40>

## Funder(s)

### Funder type

Industry

### Funder Name

Biotest AG (Germany)

### Funder Name

Sanofi Pasteur MSD GmbH (Germany)

## Results and Publications

### 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?
<a href="#">Basic results</a>			21/04/2020	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes