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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

Submission date
19/08/2008

Recruitment status
No longer recruiting

Registration date
09/10/2008

Overall study status
Completed

Last Edited
21/04/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 HBVAXPROTM on weeks 0, 2, 4, 16 and 18. One arm receives active i.m. vaccination with 10 µg HBVAXPROTM 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, pentamidin, 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, ketokonazol, itrakonazol, isoniazid, rifampicin, rifabutin, statine), 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 cytokines-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?
Basic results			21/04/2020	No	No