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German Acute Hepatitis B Study: a double-blind placebo-controlled randomised two-armed parallel-group phase IIb multi-centre trial

Submission date	Recruitment status	[_] Prospectively registered
10/01/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/05/2019	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.gahb.de

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2005-005987-94

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
German Acute Hepatitis B Study: a double-blind placebo-controlled randomised two-armed parallel-group phase IIb multi-centre trial

Acronym
GAHB-Study

Study objectives
Early intervention with the antiviral drug lamivudine leads to earlier recovery from acute hepatitis B

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of University Leipzig, approved on 29.11.2006, Bearbeitungs-Nr. 101-06 ff

Study design
Double-blind placebo-controlled randomised two-armed parallel-group phase IIb multi-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Acute Hepatitis B

Interventions
Administration of lamivudine versus placebo

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Two primary endpoints are to be considered:
1. Time until Bilirubin < 2 mg/dl
2. Time to hospital discharge
They are ranked according to their relevance and reliability

Secondary outcome measures
The secondary endpoints are grouped into three categories according to their meaning:

1. Endpoints related to antiviral response:
1.1 Time to clear HBsAg (HBsAg negative)
1.2 In initially HBeAg positive patients: Time to clear HBeAg (HBeAG negative)
1.3 Rate of HBsAg positive patients at 6 and 12 months, respectively, after start of therapy
1.4 Time to first occurrence of anti-HBs
1.5 In initially HBeAg positive patients: Time to first occurrence of anti-HBe
1.6 Time to clear HBV-DNA (HBV-DNA below level of detection)

2. Endpoints related to liver function:
2.1 Time to normalisation of prothrombin time (Quick >=70%), if initially abnormal
2.2 Time to normalisation of liver enzymes ALAT, ASAT (according to the appropriate reference levels of the central laboratory)
2.3 Rate of patients progressing to fulminant hepatitis

3. Patient related endpoints:
3.1 Rate of adverse and serious adverse events
3.2 For patients with ongoing employment relationship: time to end of absence from work

Overall study start date
31/12/2006

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Acute hepatitis
2. HBsAg positive
3. Compensated liver function (Quick > 50%)
4. Bilirubin > 5mg/dl (i.e. >85µmol/l)
5. ALAT > 10 times upper normal range
6. Age >= 18 years
7. Hospitalization caused by acute hepatitis
8. Time since diagnosis < 8 days
9. Written informed consent of the patient

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
140

Total final enrolment
35

Key exclusion criteria
1. Known or obvious pre-existing liver disease
2. Ongoing interferon therapy or stop of interferon less than 3 months ago
3. Ongoing drug abuse
4. HIV positive
5. Anti-HCV or HCV-RNA positive
6. Anti-HDV positive
7. Renal insufficiency (creatinine >1.5mg/dl or 135µmol/l)
8. Pregnant or nursing women
9. Women with child bearing potential (< 2 years after last menstruation) without effective contraception
10. Use of oral contraception
11. Patient with transplanted organs
12. Any disease requiring immunosuppressive therapy, incl. cancer chemotherapy
13. Any acute infectious disease requiring administration of sulphonamide/ trimethoprim
14. Evidence of any other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates use of an investigational drug, or patient at high risk from treatment complications
15. Known hypersensitivity to any of the study drugs or its ingredients
16. Current or recent (within 30 days prior to start of trial treatment) treatment with another investigational drug or participation in another investigational trial
17. Expected low compliance (e.g. by travel distance to trial site)

Date of first enrolment
31/12/2006

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Germany

Study participating centre
Universität Leipzig
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Germany
04103

Sponsor information

Organisation
University of Leipzig (Germany)

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Sponsor type
University/education

ROR
https://ror.org/03s7gtk40

Funder(s)

Funder type
Government

Funder Name
The GAHB-Study is funded by a grant of the Bundesministerium für Bildung und Forschung
Förderkennzeichen 01KG0507

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Results article	results	01/10/2014	09/05/2019	Yes	No