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Comparisons of the durability of 6 months versus 12 months antiviral therapy for hepatitis B after end of chemotherapy

Submission date
13/08/2021

Recruitment status
No longer recruiting

Registration date
13/10/2021

Overall study status
Completed

Last Edited
30/12/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Using chemotherapy to treat cancer has the side effect of a reduction in the body's ability to fight infection (immunosuppression). It is possible to provide some prevention of infection by giving antiviral drugs (prophylaxis antiviral therapy).
Prophylactic antiviral therapy is recommended for hepatitis B patients receiving chemotherapy but the ideal treatment duration after cessation chemotherapy lakes clinical evidence. We compare the relapse rate of 6 months and 12 months nucleoside analogues (NA) therapy in patients stratified by low HBV-DNA<2000 IU/ml or high HBV-DNA≥2000 IU/ml.

Who can participate?
Cancer patients with chronic hepatitis B receiving chemotherapy.

What does the study involve?
Participants received tenofovir or entecavir one week before chemotherapy. Following the end of chemotherapy, they were randomly allocated to receive 6 months or 12 months of NA therapy either low HBV-DNA<2000 IU/ml or high HBV-DNA≥2000 IU/ml.

What are the possible benefits and risks of participating?
Participants may benefit from tenofovir or entecavir treatment in patients with chronic hepatitis B during chemotherapy.
No definite risks known as current treatment duration is still unclear (6 or 12 months are suggested by different guidelines)

Where is the study run from?
Kaohsiung Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
September 2012 to August 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Tsung-Hui Hu, dr.hu@msa.hinet.net

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
104-7859C

Study information

Scientific Title
A prospective single-center, open-level, randomized study to compare the effectiveness of extended 6 versus 12 months tenofovir or entecavir therapy between HBV patients with cancer after completion of immunosuppressive anticancer therapy

Study objectives
Prophylactic antiviral therapy is recommended for hepatitis B patients receiving chemotherapy but the ideal treatment duration after cessation of chemotherapy lacks clinical evidence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/11/2015, Ethics Committee of Chang Gung Memorial Hospital (No 199, Dunhua N Rd. Songshan Dist. Taipei City, Taiwan; violet1202@cgmh.org.tw; +886-3-3196200 ext 3717), ref: 104-7859C

Primary study design
Interventional

Study design
Open level randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hepatitis B in patients with cancer after completion of immunosuppressive anticancer therapy

Interventions
This was a randomized, open-label study in NA-naïve HBeAg-positive and HBeAg-negative patients with CHB.
Patients received Tenofovir 300mg or Entecavir 0.5mg one week before chemotherapy and were randomized into 4 groups (using an online tool) after cessation chemotherapy:
HBV DNA <2000 IU/ml, 6-month or 12-month duration
HBV DNA ≥2000 IU/ml, 6-month or 12-month duration

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tenofovir disoproxil fumarate, entecavir

Primary outcome(s)
Virological relapse and clinical relapse rate measured using patient records at baseline, 3, 6, 9 and 12 months after cessation of antiviral therapy

Key secondary outcome(s)
1. Presence of HBsAg, HBeAg and Anti-HBe determined by commercial assays (Abbott, North Chicago, IL., USA) at baseline, 3, 6, 9 and 12 months after cessation of antiviral therapy, and then after every 6 months
2. Serum HBV DNA levels were assessed using COBAS AmpliPrep-COBAS Taqman HBV test (Roche Molecular System, Inc., Branchburg, NJ, USA), with a lower detection limit of 20IU/ml at baseline, 3, 6, 9 and 12 months after cessation of antiviral therapy, and then after every 6 months

Completion date
22/08/2017

Eligibility

Key inclusion criteria
1. Over 20 years old
2. Hepatitis B surface antigen (HBsAg) seropositive for >6 months
3. Cancer patients receiving chemotherapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
61

Key exclusion criteria
Patients who had co-infection with human immunodeficiency virus, hepatitis C virus or hepatitis D virus by serological assays

Date of first enrolment
01/01/2013

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Taiwan

Study participating centre
Kaohsiung Chang Gung Memorial Hospital
123 Ta-Pei Road Niao Sung District
Kaohsiung
Taiwan
833

Sponsor information

Organisation
Kaohsiung Chang Gung Memorial Hospital

ROR
https://ror.org/00k194y12

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			30/12/2021	No	No