

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

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<b>Registration date</b> 13/10/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/12/2021	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 lacks 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

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**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

### **Study design**

Open level randomized controlled trial

### **Primary study design**

Interventional

### **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

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# 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?
<a href="#">Protocol file</a>			30/12/2021	No	No