

# Effectiveness and safety of tenofovir disoproxil fumarate in chronic hepatitis B patients

<b>Submission date</b> 04/04/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/06/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/06/2023	<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

HBV infection is particularly important in the Asian-Pacific region and China. Tenofovir disoproxil fumarate (TDF) was approved for the treatment of Chronic Hepatitis B (CHB) in the U.S. in 2008 and in China in 2013 based on Phase III clinical trials results. Since launching in China in 2014, the treatment experience of TDF is limited due to poor access. One important reason was the lack of real-world evidence on long-term effectiveness and safety of TDF among Chinese CHB patients to guide clinical practice. The generation of real-world evidence from this study will provide clinical guidance to Chinese healthcare care professional, address their concerns, and aid public health decision making on resource allocation. To assess the effectiveness among overall and sub-group Chinese CHB patients who receive TDF treatment in real-world.

### Who can participate?

TDF-naïve patients with confirmed diagnosis of CHB who newly initiate (Viread) monotherapy or combination therapy for the treatment of CHB will be invited to participate in this study

### What does the study involve?

The study is a non-interventional real-world study, and participants will be diagnosed, treated, and monitored as in real clinical practice according to their physicians' judgement without additional interventions and procedures. Participants data will be collected from lab test reports or medical records via electronic approaches (Smartphone App) at the entry of the study and thereafter at 6-month intervals for 3 years. There are no mandatory visits during the study period, however, according to the CHB clinical practice and CHB management guideline, CHB patients on anti-viral treatment should be monitored for at least every 6 months.

### What are the possible benefits and risks of participating?

Not applicable for this non-interventional real-world study.

### Where is the study run from?

The Second Affiliated Hospital of Chongqing Medical University (China)

### When is the study starting and how long is it expected to run for?

October 2018 to December 2023

Who is funding the study?  
GlaxoSmithKline (China) Investment Co., Ltd

Who is the main contact?  
Dr Hong Ren, renhong0531@126.com

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Hong Ren

### ORCID ID

<https://orcid.org/0009-0002-0622-6062>

### Contact details

288 Tianwen Avenue  
Nan'an District  
Chongqing  
China  
400060  
+86 13983888786  
renhong0531@126.com

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Effectiveness and Safety of Tenofovir Disoproxil Fumarate in Chronic Hepatitis B Patients: A 3-Year, Prospective, Real-World Study in China

### Study objectives

To assess the effectiveness among overall and sub-group Chinese chronic hepatitis B (CHB) patients who receive tenofovir disoproxil fumarate (TDF) treatment in the real-world.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 11/09/2018, Ethics Committee of the Second Affiliated Hospital of Chongqing Medical University (288 Tianwen Avenue, Nan'an District, Chongqing, -, China; +86-023-62888436; 1270161476@qq.com), ref: 2019-7-3

## **Study design**

Multi-center prospective longitudinal observational

## **Primary study design**

Observational

## **Study type(s)**

Safety, Efficacy

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

Effectiveness and safety of tenofovir disoproxil fumarate in chronic hepatitis B patients

## **Interventions**

This was a non-interventional real-world study. Chronic Hepatitis B (CHB) patients treated with TDF were included, patient data will be collected at the entry of this study and thereafter at 6-month intervals for 3 years. Enrollment started on 16th July 2019 and ended on 30th November 2020.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

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

Tenofovir disoproxil fumarate

## **Primary outcome(s)**

Measured using patient records:

1. Complete virologic response (CVR) at weeks of 48, 96, and 144.
2. HBeAg loss and/or HBeAg seroconversion in HBeAg positive patients at weeks of 48, 96 and 144.
3. HBsAg loss and/or HBsAg seroconversion at weeks of 48, 96 and 144.
4. Transaminase normalization at weeks of 48, 96 and 144.
5. Time to CVR, defined as time from baseline to the first occurrence of CVR (if applicable)

## **Key secondary outcome(s)**

Measured using patient records:

1. eGFR at baseline, weeks 48, 96, and 144.
2. Confirmed serum phosphate Grade 3 or 4 abnormality (<2.0 mg/dL) at weeks of 48, 98 and 144.
3. Serum phosphate at baseline, weeks 48, 98 and 144.
4. Phosphorus values at baseline, weeks 48, 98 and 144.

## **Completion date**

31/12/2023

# Eligibility

## Key inclusion criteria

1. Male or female participants aged 12 years and above, at the time of signing the informed consent.
2. Participants who are diagnosed with CHB and meet the criterion of antiviral treatment for HBV infection judged by certified physicians.
3. Participants who newly initiate TDF ((only including brand TDF, Viread, and generic TDF, Beixin and Naxinde, which passed China generic quality consistency evaluation by Apr. 1 2018) monotherapy or combination therapy for the treatment of CHB by the judge of investigators at the study entry.
4. Participants who have already started TDF at the entry of study and will continue to be treated TDF (including brand TDF, Viread, and generic TDF, Beixin and Naxinde, which passed China generic quality consistency evaluation by Apr. 01 2018) with essential medical information record and lab test reports available at the initiation of TDF treatment and follow-up visit.
5. Participants who are able to perform normal activities and seek regular medical care, e.g., willing to regularly perform lab test to monitor the treatment response.
6. Participants or their legal guardians who are capable of providing signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Mixed

## Sex

All

## Total final enrolment

2000

## Key exclusion criteria

1. Participants who have HIV/HCV co-infection.
2. Participants who initiate or continue antiviral treatment of generic TDF which did not pass China generic quality consistency evaluation by Apr. 01, 2018
3. Participants who initiate antiviral treatment of unauthorized TDF in China.
4. Participants with a prior history of receiving any TDF monotherapy or combination therapy without essential lab test report (e.g. HBV DNA level, eGFR, serum phosphate) and medical records available at the initiation of TDF treatment and thereafter follow-up.
5. Participants who participate in any concurrent clinical trials or within 3 months prior to the entry into this study.
6. Participants who are NOT able to upload their information electronically using the study-designed smartphone APP.
7. Inability to comply with study requirements as determined by the study Investigator.

## Date of first enrolment

16/07/2019

**Date of final enrolment**

30/11/2020

## **Locations**

**Countries of recruitment**

China

**Study participating centre**

**The Second Affiliated Hospital of Chongqing Medical University**

288 Tianwen Avenue, Nan'an District

Chongqing

China

400060

**Study participating centre**

**The Fourth Affiliated Hospital of Xinjiang Medical University**

No.116, Huanghe road

Shayibake district

Urumqi

Xinjiang

China

830000

**Study participating centre**

**The Third People's Hospital of Taiyuan**

No.65, Shuangta west street

Taiyuan

China

030000

**Study participating centre**

**The Fourth Affiliated Hospital of Harbin Medical University**

No.37 Yiyuan street

Nangang district

Harbin

China

150000

**Study participating centre**  
**Shenyang Sixth People's Hospital**  
No.85 Heping south street  
Heping district  
Shenyang  
China  
110000

**Study participating centre**  
**Tianjin Second People's hospital**  
No.75, Sudi south road  
Nankai district  
Tianjin  
China  
300000

**Study participating centre**  
**The Third People's Hospital Of KunMing**  
No.319, Wujing road  
Guandu district  
Kunming  
China  
650000

**Study participating centre**  
**Qiqihar Seventh Hospital**  
No.88 Xinming street  
Qiqihar city  
Qiqihar  
China  
161000

**Study participating centre**  
**The Second Affiliated Hospital of the Air Force Military Medical University**  
No.1, Xinsi road  
Baqiao district  
Xi'an  
China  
710000

**Study participating centre**

**Beijing You'an Hospital Affiliated to Capital Medical University**

No.8, xitoutiao, you 'an men wai

Fengtai district

Beijing

China

100000

**Study participating centre**

**Nanchang Ninth Hospital**

167 Hongdu middle avenue

Nanchang

China

330000

**Study participating centre**

**Affiliated Hospital of Yunnan University**

176 Qingnian road

Kunming

China

650000

**Study participating centre**

**Jilin Provincial Hepatobiliary Hospital**

No. 2218, Jingyang road

Changchun

China

130000

**Study participating centre**

**Nanjing Gulou Hospital**

321 Zhongshan road

Nanjing

China

230000

**Study participating centre**

**Shenzhen Third People's Hospital**

No. 29, Bulan road

Longgang district

Shenzhen  
China  
518000

### Study participating centre

**Tongji Hospital affiliated to Tongji Medical College, Huazhong University of Science and Technology**  
1095 Jiefang avenue  
Wuhan  
China  
430000

## Sponsor information

### Organisation

GlaxoSmithKline (China) Investment Co., Ltd.

## Funder(s)

### Funder type

Industry

### Funder Name

GlaxoSmithKline (China) Investment Co., Ltd

## 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

Published as a supplement to the results publication

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>		09/11/2018	13/06/2023	No	No