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Study Comparing Tenofovir Disoproxil Fumarate (TDF), Emtricitabine/TDF, & Entecavir in the Treatment of Chronic HBV in Subjects w/Decompensated Liver Disease.

This study is ongoing, but not recruiting participants.

Sponsored by:	Gilead Sciences
Information provided by:	Gilead Sciences
ClinicalTrials.gov Identifier:	NCT00298363

► Purpose

The study is designed to evaluate and compare the safety and tolerability of tenofovir disoproxil fumarate (DF), emtricitabine/tenofovir DF, and entecavir in the treatment of hepatitis B patients with decompensated liver disease.

Condition	Intervention	Phase
Chronic Hepatitis B	Drug: tenofovir disoproxil fumarate Drug: emtricitabine / tenofovir disoproxil fumarate Drug: entecavir	Phase II

[MedlinePlus](#) related topics: [Hepatitis](#) [Hepatitis B](#)

[ChemIDplus](#) related topics: [Hepatitis B Vaccines](#) [Tenofovir disoproxil](#) [2'-Deoxy-5-fluoro-3'-thiacytidine](#) [Truvada](#)

[U.S. FDA Resources](#)

Study Type: Interventional

Study Design: Treatment, Randomized, Double Blind (Subject, Investigator, Outcomes Assessor), Active Control, Parallel Assignment, Safety/Efficacy Study

Official Title: Phase 2, Double-Blind, Multi-Center, Randomized Study Comparing Tenofovir Disoproxil Fumarate, Emtricitabine/Tenofovir Disoproxil Fumarate, and Entecavir in the Treatment of Chronic Hepatitis B Subjects With Decompensated Liver Disease and in the Prevention of Hepatitis B Recurrence Post-Transplantation.

Further study details as provided by Gilead Sciences:

Primary Outcome Measures:

- Safety (adverse events and laboratory tests, discontinuations due to adverse events) [Time Frame: Week 48]
[Designated as safety issue: Yes]

Estimated Enrollment: 100

Study Start Date: March 2006

Estimated Study Completion Date: December 2010

Estimated Primary Completion Date: December 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
1: Experimental tenofovir disoproxil fumarate 300 mg tablet, once-daily	Drug: tenofovir disoproxil fumarate 300 mg tablet, once-daily
2: Experimental emtricitabine / tenofovir disoproxil fumarate 200 mg tablet / 300 mg tablet, once daily (combination pill)	Drug: emtricitabine / tenofovir disoproxil fumarate 200 mg tablet / 300 mg tablet, once daily (combination pill)
3: Experimental entecavir	Drug: entecavir 0.5 or 1 mg tablet, once daily

0.5 or 1 mg tablet, once daily

Detailed Description:

Safety will be assessed by evaluating adverse events, laboratory abnormalities and the development of drug-resistant mutations. Efficacy will be evaluated for reductions in Child-Pugh-Turcotte (CPT) and Model for End Stage Liver Disease (MELD) scores, reductions in HBV DNA, changes in liver enzymes, and the generation of antibody to virus.

 **Eligibility**

Ages Eligible for Study: 18 Years to 69 Years
Genders Eligible for Study: Both

Criteria

Inclusion Criteria:

A patient must meet all of the following inclusion criteria to be eligible for participation in the study.

- Chronic Hepatitis B infection.
- 18 through 69 years of age, inclusive.
- HBV DNA \geq 1000 copies/mL.
- Decompensated liver disease with all of the following:
 - CPT score of 7-12 (inclusive) OR a past history of CPT score \geq 7 and any CPT at screen \leq 12.
 - Serum ALT $<$ 10 x ULN.
 - Hemoglobin \geq 7.5 g/dL.
 - Total WBC count \geq 1,500/mm³.
 - Platelet count \geq 30,000/mm³.
- Alpha-fetoprotein \leq 20 ng/mL and ultrasound or other imaging with no evidence of HCC, or alpha-fetoprotein of 21-50 ng/mL and CT/MRI with no evidence of HCC, within 6 months of screening.
- Calculated creatinine clearance \geq 50 mL/min.
- Negative HIV, HCV and HDV serologies.
- Less than 24 months of total prior adefovir dipivoxil exposure.

Exclusion Criteria:

A patient who meets any of the following exclusion criteria cannot be enrolled in the study:

- Pregnant women, women who are breastfeeding or who believe they may wish to become pregnant during the course of the study.
- Males and females of reproductive potential who are unwilling to use an "effective" method of contraception during the study.
- Prior use of tenofovir DF or entecavir.
- History of variceal bleeding, hepatorenal syndrome, Grade 3 or Grade 4 hepatic encephalopathy, or spontaneous bacterial peritonitis within 60 days of screening.
- Grade 2 hepatic encephalopathy at screening
- History of solid organ or bone marrow transplant.
- Current use of hepatotoxic drugs, nephrotoxic drugs, or drugs that interfere with renal tubular secretion.
- Current therapy with immunomodulators (e.g., corticosteroids, IL-2, etc) or investigational drugs.
- Diagnosis of proximal tubulopathy.
- Use of investigational agent within 30 days prior to screening.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00298363

[Hide Study Locations](#)

Locations

United States, California

Los Angeles, California, United States, 90095
San Francisco, California, United States, 94115
San Diego, California, United States, 92103

United States, Florida

Jacksonville, Florida, United States, 32216
Miami, Florida, United States, 33136

United States, Michigan

Detroit, Michigan, United States, 48202

United States, New York

New York, New York, United States, 10032

New York, New York, United States, 10029

United States, Texas

Houston, Texas, United States, 77030

United States, Virginia

Annandale, Virginia, United States, 22003

Fairfax, Virginia, United States, 22031

United States, Washington

Seattle, Washington, United States, 98104

Canada, Alberta

Calgary, Alberta, Canada, T2N4N1

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z1H2

Vancouver, British Columbia, Canada, V5Z3P1

Canada, Ontario

Toronto, Ontario, Canada, M5G 2C4

France

Clichy, France, 92210

Lyon, France, 69288

Marseille, France, F13385

Villejuif, France, 94800

Germany

Berlin, Germany, 13353

Hamburg, Germany, 20251

Hannover, Germany, 30623

Heidelberg, Germany, 69120

Mainz, Germany, 55131
Frankfurt, Germany, 60590

Greece

Thessaloniki, Greece, 570 10
Thessaloniki, Greece, 546 42
Athens, Greece, 115 27

Ireland

Dublin, Ireland

Italy

Padova, Italy, 35123
Padova, Italy, 35128
Torino, Italy, 10134
Udine, Italy, 33100

Poland

Bialystok, Poland, 15-540
Bydgoszcz, Poland, 85-030
Warsaw, Poland, 01-201

Singapore

Singapore, Singapore, 119074
Singapore, Singapore, 169608
Singapore, Singapore, 529889
Singapore, Singapore, 308433

Spain

Barcelona, Spain, 08035
Barcelona, Spain, 08907
Barcelona, Spain, 08036
Madrid, Spain, 28007
Valencia, Spain, 46009

Taiwan

Tainan, Taiwan, 704
Taoyuan Hsien, Taiwan, 333
Taipei City, Taiwan, 114
Kaoshiung Hsien, Taiwan, 833
Taipei, Taiwan

Turkey

Ankara, **Turkey**
Izmir, **Turkey**
Besevler -Ankara, **Turkey**, 06510
Bursa, **Turkey**, 16059
Istanbul, **Turkey**

Sponsors and Collaborators

Gilead Sciences

Investigators

Study Chair: Elsa Mondou, M.D. Gilead Sciences

More Information

Responsible Party: University of Miami (Eugene Schiff)
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First Received: February 28, 2006
Last Updated: January 4, 2008
ClinicalTrials.gov Identifier: [NCT00298363](https://clinicaltrials.gov/ct2/show/study/NCT00298363)
Health Authority: United States: Food and Drug Administration

Keywords provided by Gilead Sciences:
Hepatitis; Hepatitis B virus; Tenofovir

Study placed in the following topic categories:

Communicable Diseases	Entecavir
Liver Diseases	Emtricitabine
Hepatitis, Chronic	Hepatitis B, Chronic

Hepatitis, Viral, Human
Infection
Recurrence
Hepatitis

Hepatitis B
Tenofovir
DNA Virus Infections
Tenofovir disoproxil

Additional relevant MeSH terms:

Anti-Infective Agents
Anti-HIV Agents
Enzyme Inhibitors
Hepadnaviridae Infections
Antiviral Agents
Pharmacologic Actions
Molecular Mechanisms of Action

Reverse Transcriptase Inhibitors
Virus Diseases
Digestive System Diseases
Anti-Retroviral Agents
Therapeutic Uses
Nucleic Acid Synthesis Inhibitors

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