

What current treatments are available for hepatitis D?

Hepcludex (formerly Myrcludex B) is the first drug in the world to be approved for treatment of hepatitis delta. It was approved for prescription in Europe in July of 2020 and MYR Pharmaceuticals (recently acquired by Gilead Sciences) will be working to seek approval in other parts of the world throughout 2021. Hepcludex works as an entry inhibitor, preventing hepatitis delta cells from infecting healthy liver cells. Prior to the introduction of Hepcludex, pegylated interferon (PEG-IFN) has often been and continues to be used in hopes of stimulating the body's immune system to fight the virus. A small percentage of patients (<30%) experience remission when injected with PEG-IFN weekly over 48 weeks. Oral nucleosides (antivirals) approved for hepatitis B have no effect on hepatitis D.

What new drugs are in clinical trials for hepatitis D?

There are currently 6 new drugs in clinical trials being tested for effectiveness against the hepatitis D virus.

Drug	Mechanism	Company	Clinical Trial Phase	Designations
Lonafarnib	Prenylation Inhibitor	Eiger BioPharma, USA	Phase III	FDA Breakthrough Therapy Designation FDA Fast Track Designation FDA Orphan Drug Designation EMA Orphan Drug Designation EMA PRIME
Hepcludex (Formerly Myrcludex B)	Entry Inhibitor	MYR-GmbH, Germany (now part of Gilead)	Phase III	EMA PRIME FDA Breakthrough Therapy Designation FDA Orphan Drug Designation Promising Innovative Medicine (PIM) Designation by British MHRA
Lambda (Pegylated Interferon)	Immune Response Stimulator	Eiger BioPharma, USA	Phase III Ready	FDA/EMA Orphan Drug Designation FDA Fast Track Designation FDA Breakthrough Therapy Designation
Ezetimibe	NTCP Inhibitor	Ziauddin University Hospital, Pakistan	Phase II	N/A
REP 2139 - Mg (in combination with PEG-INF and Tenofovir)	HBsAg Inhibitor	Replicor, Canada	Phase II	N/A
GI-18000	Immune Response Stimulator	Globelimmune, USA	Pre-clinical	N/A

Lonafarnib PHASE 3

Lonafarnib is a "prenylation inhibitor" that works by targeting the protein assembly process, which prevents new virus from being created. In a recent study, Lonafarnib combined with Ritonavir showed promise in reducing hepatitis D virus levels.

Hepcludex (formerly Myrcludex B) PHASE 3

Hepcludex is an "entry inhibitor" that works by stopping the virus from entering and infecting hepatocytes (liver cells) and breaking the cycle of reinfection. It has shown activity against the hepatitis B virus, and has been approved for treatment of hepatitis D. The purpose of the Phase III trials are to evaluate the long-term effects of this drug.

Pegylated Interferon Lambda (PEG-IFN-λ) PHASE 3 READY

Pegylated Interferon Lambda is a type III interferon that works by activating the body's own immune system to fight the virus. A recent study showed the ability of combination therapy with ritonavir and Lonafern to reduce hepatitis D virus levels.

Ezetimibe PHASE 2

Ezetimibe is a pill currently being used as a treatment to lower cholesterol. Now being studied for effectiveness against hepatitis D, it works by inhibiting NTCP, the receptor required for hepatitis D to enter and infect liver cells.

Rep 2139 (in combo w/ PEG INF & Tenofovir) PHASE 2

REP 2139 is a "nucleic acid-based amphipathic polymer (NAP)", taken as a pill, that work by preventing infected liver cells from releasing hepatitis B virus into non-infected liver cells. It is being evaluated for use in combination with PEG-IFN.

GI-18000 PRE-CLINICAL

GI-18000 is an "immune response stimulator", taken as a pill, that works by causing the host's T-cells to target and fight the hepatitis B- and D-infected liver cells.

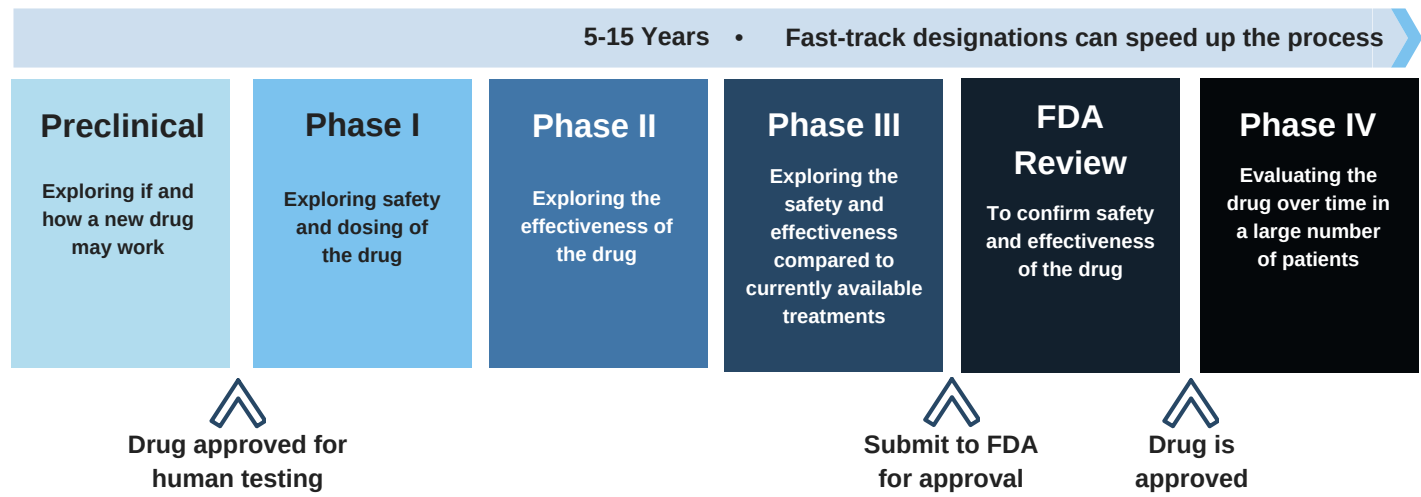
How can patients locate clinical trial sites?

Patients can search open and upcoming clinical trials on the [Clinicaltrials.gov](https://www.clinicaltrials.gov) website. For detailed instructions on searching and locating clinical trials, visit our helpful guide, found at <https://www.hepb.org/research-and-programs/hepdeltaconnect/clinical-trials/>. Patients should also discuss the possibility of participating with their doctors, and see if their doctor can connect them with a local trial.

How long will it take for new treatments to be available for all patients?

In the United States, new drugs must go through a multi-phase clinical trial process in order to test a drug's usefulness, safety and effectiveness before it is made available to all patients. Drugs face many obstacles during this process and not all of them may make it to the patient market. While this process can take anywhere from 5-15 years, fast-track and priority designations can speed up the process.

Clinical Trial Process



The Hepatitis B Foundation is a national nonprofit research and disease advocacy organization for hepatitis B. It established Hepatitis Delta Connect as a dedicated program in 2016 to provide information and support for those affected by hepatitis D.