Hepatitis D
Treatment and Clinical Trials

What current treatments are available for hepatitis D?

Currently, there is only one approved treatment for hepatitis D, pegylated interferon (PEG-IFN). It acts by stimulating the body's immune system to fight the virus. A small percentage of patients (<30%) experience remission when injected weekly over 48 weeks. Emerging research is showing higher success rates with injections longer than 1 year. 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 7 drugs in clinical trials being tested for effectiveness against the hepatitis D virus (HDV).

DRUG	MECHANISM	COMPANY	STATUS
Lonafarnib	Prenylation Inhibitor	Eiger BioPharma, USA	*FDA Breakthrough Therapy Designation* *FDA Fast Track Designation* *FDA Orphan Drug Designation* *EMA Orphan Drug Designation* *EMA PRIME* **Phase III**
Lambda (Pegylated Interferon)	Immune Response Stimulator	Eiger BioPharma, USA	*FDA Orphan Drug Designation* *FDA Fast Track Designation* **Phase II**
Myrcludex B	Entry Inhibitor	MYR-GmbH, Germany	*EMA PRIME* *FDA Breakthrough Therapy Designation* *FDA Orphan Drug Designation* **Phase III (Projected 2019)**
Ezetimibe	NTCP Inhibitor	Ziauddin University Hospital, Pakistan	**Phase II**
REP 2139 **REP 2165**	HBsAg Inhibitor	Replicor, Canada	**Phase II**
GI-18000	Immune Response Stimulator	GlobeImmune, USA	**Pre-clinical**
ALN-HDV	RNAi Gene Silencer	Alnylam, USA	**Pre-clinical**
N/A	RNA Interference	Somagenetics, USA	**Pre-clinical**

Lonafarnib

This drug works by targeting the protein assembly process, preventing the production of new virus particles. In a current clinical trial, Lonafarnib combined with Ritonavir has shown promise in reducing hepatitis D viral levels, and the Food and Drug Administration (FDA) has granted it "Fast-Track" status, "Breakthrough Therapy Designation" and "Orphan Drug Designation" as this class of drugs have been developed for the treatment of cancers and have been shown to be safe.

Pegylated Interferon Lambda

Pegylated-interferon-lambda (PEG-IFN-λ) is a well-characterized, late-stage, first in class, type III interferon that stimulates cell-mediated immune responses that are critical for the development of host protection during viral infections. This drug is now granted "Orphan Drug Designation" and "Fast-Track Designation" by the FDA.

Myrcludex B

This drug is an “entry inhibitor” that inhibits virus entry into hepatocytes (liver cells) and has shown activity against the hepatitis B virus. It may also hinder the establishment of HDV infection by breaking the cycle of infection of the liver cell and possibly re-infection. A recent study showed promise for Myrcludex B when combined with PEG-INF in reducing hepatitis D viral levels. It has been granted PRIME Eligibility by the European Medicines Agency, a status that promotes support in development of drugs that target an unmet medical need.

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.

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Ezetimibe
Currently used to lower cholesterol in the blood, Ezetimibe is being studied for effectiveness against hepatitis D. Ezetimibe possesses pharmacophore features to inhibit NTCP, the receptor required for HBV and HDV hepatocyte entry.

Rep 2139
This compound is known as a “Nucleic acid-based Amphipathic Polymer” (NAP) which inhibits the release of hepatitis B surface antigen (HBsAg) from infected liver cells and is being evaluated for hepatitis D virus in combination with PEG-IFN.

GI-18000
GI-18000 Tarmogen is being studied for its effectiveness in causing a T cell immune response against cells infected with Hepatitis D to improve outcomes. The strategy is to identify molecular targets that distinguish diseased cells from normal cells and activate the immune system to selectively target and eliminate only the diseased cells.

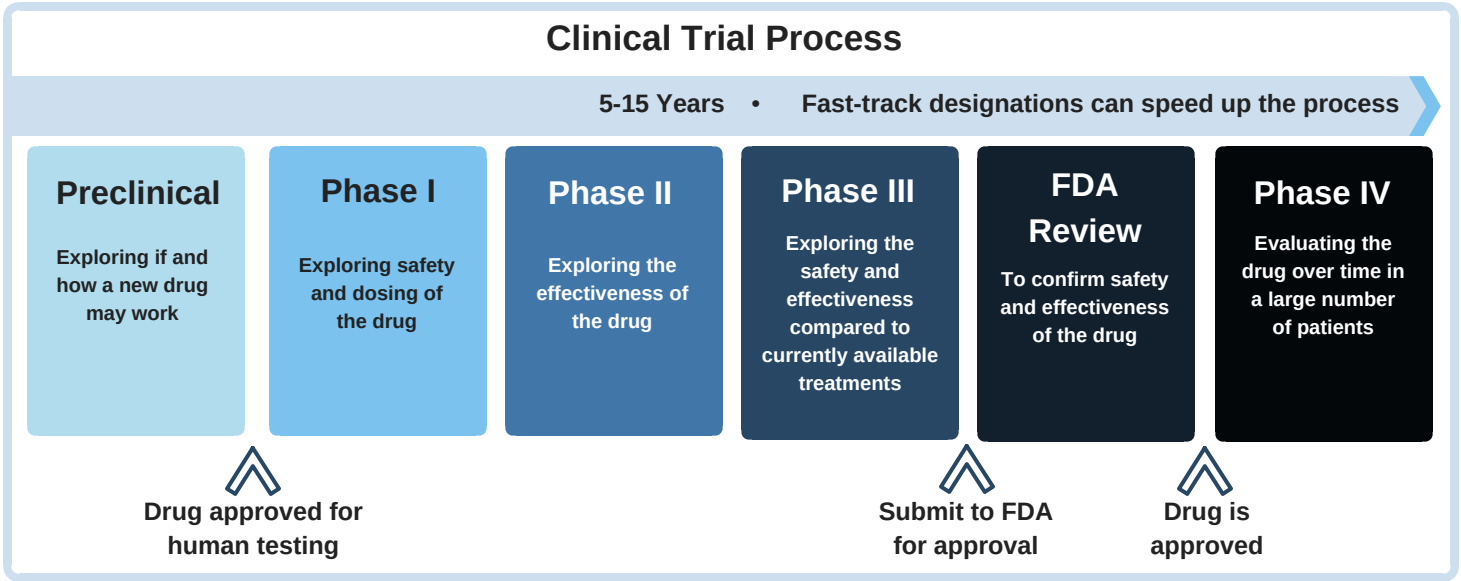
ALN-HDV
This approach is being used for both the hepatitis B and hepatitis D virus to "silence" the viral RNA with compounds that interfere with and cause the destruction of the viral genome.

How can patients locate clinical trial sites?

Patients can search open and upcoming clinical trials on the **Clinicaltrials.gov** website. For detailed instructions on searching and locating clinical trials, visit our helpful **guide**. Patients should also discuss with their doctors the possibility of participating, 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.



It is important for patients to stay informed and up-to-date on clinical trials while waiting for more treatment options!

Visit www.clinicaltrials.gov for more information.

HEPATITIS B FOUNDATION

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