HEPATITIS DELTA CONNECT
hepdconnect.org

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 currently 7 new drugs in clinical trials being tested for effectiveness against the hepatitis D virus.

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**
Myrcludex B	Entry Inhibitor	MYR-GmbH, Germany	*EMA PRIME* *FDA Breakthrough Therapy Designation* *FDA Orphan Drug Designation* **Phase III (Projected 2019)**
Lambda (Pegylated Interferon)	Immune Response Stimulator	Eiger BioPharma, USA	*FDA Orphan Drug Designation* *FDA Fast Track Designation* *FDA Breakthrough Therapy Designation* **Phase II**
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**

Lonafarnib PHASE 3

Lonafarnib is a "prenylation inhibitor", taken as a pill, 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.

Myrcludex B PHASE 3

Myrcludex B is an “entry inhibitor”, taken as a pill, that 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, but is also being tested for effectiveness against hepatitis D. A recent study showed promise for Myrcludex B when combined with PEG-INF in reducing hepatitis D virus levels.

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

Pegylated Interferon Lambda is a type III interferon, taken as an injection, that works by activating the body's own immune system to fight the virus. A recent study showed

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 & 2165 PHASE 2

REP 2139 and REP 2165 are "nucleic acid-based amphipathic polymers (NAPs)", taken as a pills, that work by preventing liver cells from releasing hepatiitis B virus into 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.

ALN-HDV PRE-CLINICAL

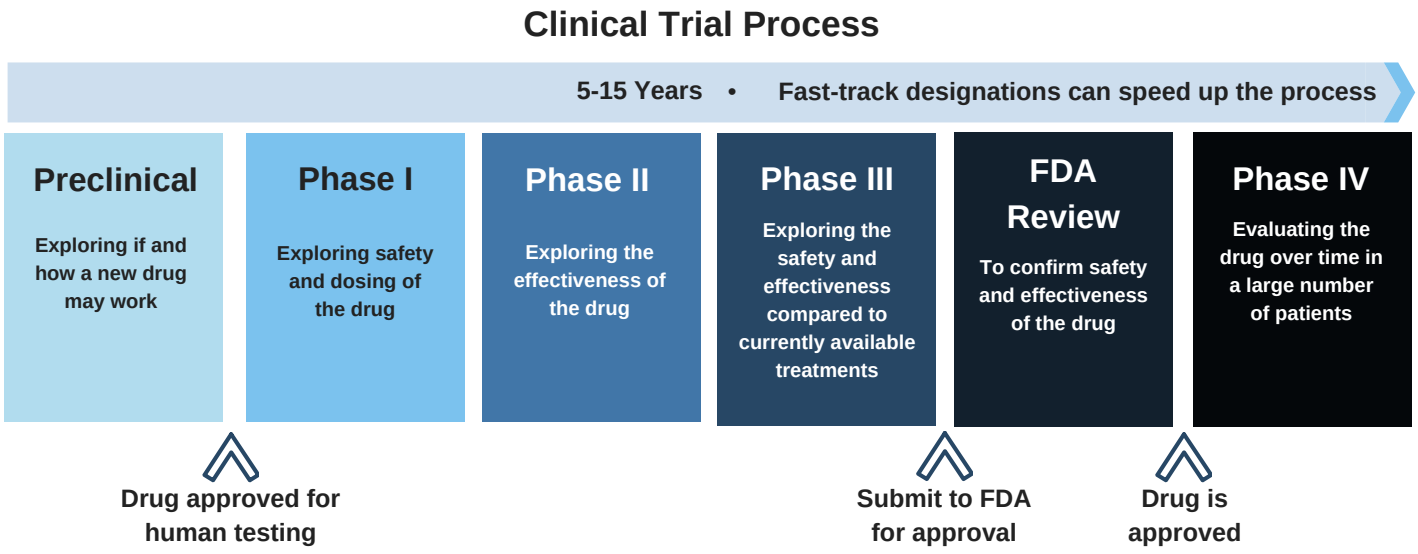
ALN-HDV is an "RNA gene silencer", taken as a pill, which works by "silencing" the viral RNA with compounds that interfere with, and cause the destruction of the virus genetics.

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.



HEPATITIS B FOUNDATION

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.