

New combination drug therapy proves very effective in Hepatitis C treatments

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Treatment options for the 170 million people worldwide with chronic Hepatitis C Virus (HCV) are evolving rapidly, although the available regimens often come with significant side effects. Two multi-center clinical trials led by Beth Israel Deaconess Medical Center show promise for a new option that could help lead to both an increase in patients cured with a much more simple and tolerable all oral therapy.

A new 12-week single tablet regimen of ledipasvir and sofosbuvir have proven to be highly effective in treating a broad range of patients with HCV genotype 1, a form of the virus found in up to 75 percent of infections, according to results unveiled today at the European Association for the Study of the Liver and published simultaneously online by the *New England Journal of Medicine*.

Between 94 percent and 99 percent of patients were cured of [hepatitis C](#) and results were similar in patients who have never been treated and for those who had previously been treated with a combination of peginterferon and ribavirin, the current course that carries sometimes significant [side effects](#).

"Eliminating interferon and ribavirin from [treatment](#) regimens is expected to reduce the incidence and severity of adverse events, to simplify the treatment of patients with HCV infection and to provide an option for patients who are ineligible for the current interferon-based treatments," said Nezam Afdhal, MD, the senior author of the studies, Director of the Liver Center at Beth Israel Deaconess Medical Center

and a Professor of Medicine at Harvard Medical School.

Hepatitis C is an infectious disease primarily affecting the liver and which can lead to scarring and cirrhosis and is transmitted primarily through blood transfusions (prior to 1991), intravenous drug use, poorly sterilized medical equipment and sexual transmission. After exposure 80 percent of patients develop a [chronic hepatitis](#) which can lead to cirrhosis, liver failure and liver cancer and hepatitis C is the most common cause for liver transplantation in the US.

Prior treatments have been with interferon which is an injectable cytokine released in response to viral infections. Interferon is combined with other antiviral agents and needs to be used for up to 48 weeks to cure hepatitis C. but is associated with number of side effects, including influenza-like symptoms depression and anemia. Many patients are ineligible for these interferon-based therapies.

"The real advances seen in the ION trials is that the sofosbuvir-ledipasvir combination tablet enables us to treat almost all genotype 1 patients with a short duration of 8-12 weeks of treatment expanding the treatment pool and increasing the overall cure rate," said Afdhal.

Recent recommendations by the CDC and endorsed by the USPHS Task force have recommended screening of baby boomers (persons born between 1945 and 1965) for hepatitis C since up to 3 percent may have silent infection without symptoms.

"Screening for HCV needs to be associated with a safe and effective treatment for these "baby boomers" with newly identified HCV and the ION trials clearly give an exciting new option for these patients" stated Afdhal.

ION-1 (865 patients) and ION-2 (440 patients) evaluated 12 and 24

weeks of sofosbuvir-ledipasvir single dose treatment for 12 versus 24 weeks either with or without ribavirin in [patients](#) who had never been treated (Ion 1) and in prior treatment failures (Ion 2). Both studies showed that 12 weeks of sofosbuvir and ledipasvir without ribavirin was adequate to cure over 95 percent of patient with hepatitis C.

More information: "Ledipasvir and Sofosbuvir for 8 or 12 Weeks for Chronic HCV without Cirrhosis." Kris V. Kowdley, et al. *NEJM* April 11, 2014 DOI: 10.1056/NEJMoa1402355

"Ledipasvir and Sofosbuvir for Previously Treated HCV Genotype 1 Infection." Nezam Afdhal, M.D., et al. *NEJM* 2014; 370:1483-1493 April 17, 2014 DOI: 10.1056/NEJMoa1316366

Provided by Beth Israel Deaconess Medical Center

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