

# Newly approved all-oral hep C combination drug found more effective in head-to-head comparison

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Findings presented today from a Phase 3 head-to-head study that compared two direct-acting antiviral treatment regimens, demonstrated that the all-oral, once daily combination of elbasvir and grazoprevir was more effective and safer than the combination of sofosbuvir and pegylated interferon with ribavirin, in certain patients with Hepatitis C (HCV).

The results were shared at The International Liver Congress 2016 in Barcelona, Spain. The combination of elbasvir and grazoprevir - recently approved by the US Food and Drug Administration and Health Canada in January 2016 - is an all-oral once a day treatment that is taken over a 12 to 16 week course.<sup>1,2</sup>

The combination of sofosbuvir and pegylated [interferon](#) with ribavirin was previously recommended by [treatment guidelines](#), however the guidelines have since been updated and no longer recommend this treatment combination. In the United States, genotype 1 HCV is the most common infection, accounting for approximately 70 to 75% of all HCV infections.<sup>3</sup> HCV genotype 4 is less prevalent in the United States, however there is a high frequency of this strain in Egypt and Africa.<sup>4</sup>

"We have recently seen a great increase in the overall number of studies investigating different direct-acting antiviral treatment regimens for Hepatitis C, but direct comparative studies are lacking," said study lead

author Dr Jan Sperl, from the Institute for Clinical and Experimental Medicine, Prague, Czech Republic. "The combination of elbasvir and grazoprevir has shown to be more effective than previously recommended treatment options, giving physicians another treatment option against this damaging infection."

The C-EDGE head-to-head study was a randomised, parallel-group trial that enrolled patients with HCV genotypes 1 and 4 who either had never received treatment or had prior unsuccessful treatment with pegylated interferon and ribavirin. Patients were randomised 1:1 to receive either 12 weeks of the combination of elbasvir/grazoprevir, or the sofosbuvir, pegylated interferon and ribavirin regimen. The primary efficacy endpoint of the study was achievement of a sustained virologic response (negative virus in the blood) at 12 weeks after the end of therapy (SVR12).

Results show that the elbasvir/grazoprevir combination was effective in HCV genotypes 1 and 4 with fewer overall side effects than the sofosbuvir, pegylated interferon combination and ribavirin combination.

The combination of elbasvir and grazoprevir resulted in an SVR12 of 99.2% (128/129) compared to 90.5% (114/126) in the sofosbuvir/pegylated interferon/ribavirin group. Elbasvir and grazoprevir demonstrated superior efficacy especially in subgroups of patients considered as hard-to-treat in the past (in cirrhotics, patients with high initial viremia and in previous null-responders to pegylated interferon and ribavirin). Furthermore, elbasvir and grazoprevir demonstrated a superior safety profile compared to sofosbuvir/pegylated interferon/ribavirin. This is primarily due to the absence of adverse effects commonly associated with pegylated interferon and/or [ribavirin](#), including low red blood cell count, low white blood cell count, flu-like illness, and pyrexia.

"A great wealth of data now exists on treatment approaches in HCV and these findings give the medical community another effective option in the [treatment](#) of this harmful disease," said Professor Laurent Castéra, EASL Secretary General.

**More information: References:**

1 Hepatitis C online. Elbasvir-Grazoprevir (Zepatier). Available from: [www.hepatitisc.uw.edu/page/treatment-elbasvir-grazoprevir](http://www.hepatitisc.uw.edu/page/treatment-elbasvir-grazoprevir). Last accessed: March 2016.

2 FDA. FDA approves Zepatier for treatment of chronic hepatitis C genotypes 1 and 4. Available from: [www.fda.gov/NewsEvents/Newsroom/ucm483828.htm](http://www.fda.gov/NewsEvents/Newsroom/ucm483828.htm). Last accessed: March 2016.

3 Hepatitis C online. Core Concepts. Treatment of HCV Genotype 1. [www.hepatitisc.uw.edu/go/treatment-1/core-concept/all](http://www.hepatitisc.uw.edu/go/treatment-1/core-concept/all). Last accessed: March 2016.

4 US National Library of Medicine National Institutes of Health. Prevalence and treatment of hepatitis C virus genotypes 4, 5, and 6. Available from: [www.ncbi.nlm.nih.gov/pubmed/16234071](http://www.ncbi.nlm.nih.gov/pubmed/16234071). Last accessed: March 2016.

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