

Trial finds drug safe and effective in treating hepatitis C during pregnancy

July 27 2020



Electron micrographs of hepatitis C virus purified from cell culture. Scale bar is 50 nanometers. Credit: Center for the Study of Hepatitis C, The Rockefeller University.

Critics of the new recommendation to screen all pregnant women for hepatitis C—a lifelong infection that attacks the liver—argue that it's wasteful to test for a disease among a population that can't be treated, but results of a small phase I clinical trial at Magee-Womens Research

Institute (MWRI) suggest otherwise: pregnancy could be an excellent time to diagnose and cure hepatitis C infection.

The results of the trial, published today in *The Lancet Microbe*, show that the antiviral drug cocktail ledipasvir/sofosbuvir resulted in 100% hepatitis C cure rate among nine pregnant volunteers, and none of their babies contracted the virus. The babies all developed normally and had no apparent adverse effects from the medication.

"People worry about the risk of antivirals on the baby but don't consider the psychosocial opportunity of pregnancy," said lead author Catherine Chappell, M.D., M.S., assistant professor of obstetrics, gynecology and reproductive sciences at the University of Pittsburgh School of Medicine and MWRI. "Pregnancy is a time when [women](#) are regularly engaged in [health care](#) and motivated to make positive changes to support their growing families. It could be a window of opportunity for these women to get a fresh start, infection-free, both for their own health and the health of their babies."

Eight out of the nine study participants contracted hepatitis C from intravenous drug use, and many came to the trial through the Pregnancy and Womens Recovery Center (PWRC) at UPMC Magee-Women's Hospital, where women can get comprehensive and compassionate care for opioid use disorder.

Although these programs can help manage and treat the chronic disease of addiction, without treatment specific to hepatitis C, the virus lingers. As a result, women may feel ongoing stigma, guilt or shame. There's also about a 6% chance that a [pregnant woman](#) will pass hepatitis C on to her child.

Ledipasvir/sofosbuvir works by blocking the viral proteins that hepatitis C uses to replicate inside cells. Since the mechanism is specific to the

virus, the side effects are minimal, Chappell said.

"The only concern we had is that sofosbuvir is excreted by the kidneys, and during pregnancy the kidneys are working on overdrive," Chappell said. "They flush medicine out more quickly than otherwise, so we were a little worried that if participants had a significant decrease in this drug that it wouldn't be as effective."

Turns out, [pregnant women](#) who received the standard dose had just as much active drug in their system as reported for non-pregnant women.

Despite the promising results in these nine volunteers, Chappell warns that more study is needed before antiviral medications can be widely prescribed to pregnant women. But in service of that goal, she is joining a multicenter phase II clinical trial that will test the safety and efficacy of these drugs in dozens of [hepatitis C](#) positive pregnant women across the country.

More information: This study was funded by the National Institute of Child Health and Human Development (grant R21HD089457), the Office of Research on Women's Health (K12HD043441) and Gilead Sciences (CO-US-3 37-2117).

Additional authors include Kimberly Scarsi, Pharm.D., of the University of Nebraska Medical Center; Brian Kirby, Ph.D., Vithika Suri, M.Sc., Anuj Gaggar, M.D., of Gilead Sciences; and Debra Bogen, M.D., Ingrid Macio, Leslie Meyn, Ph.D., Katherine Bunge, M.D., Elizabeth Krans, M.D., and Sharon Hillier, Ph.D., all of Pitt.

Gilead Sciences sells ledipasvir/sofosbuvir under the brand name Harvoni. Although Gilead provided funding as well as guidance about how best to administer the drug to unique populations, the company had no influence over the study design, data collection, analysis or

interpretation.

Provided by University of Pittsburgh

Citation: Trial finds drug safe and effective in treating hepatitis C during pregnancy (2020, July 27) retrieved 3 May 2024 from <https://medicalxpress.com/news/2020-07-trial-drug-safe-effective-hepatitis.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.