

New study looks at drug exposures of COVID-19 therapy for pregnant people

August 13 2024, by Julia Milzer



Credit: CC0 Public Domain

A new study provides important insights into the pharmacokinetics and safety of intravenous remdesivir in treating the SARS-CoV-2 coronavirus in pregnant women.

Remdesivir is an antiviral medication and is used to treat certain patients

with COVID-19 who are either hospitalized or have mild-to-moderate symptoms in the outpatient setting and are at high risk of severe disease.

The study, [published](#) in *The Journal of Infectious Diseases*, is the first pharmacokinetic study to be published on a COVID-19 therapy in [pregnant women](#). Pharmacokinetic studies help researchers understand the concentrations of drugs in the blood, how they distribute through and get eliminated from the body and whether the doses of medications are within a safe and effective range to help treat the condition they are being used for.

"Pregnant people are often left behind in [clinical research](#), and because of this, there's usually not much supporting data available for health care providers about the appropriate dosage, safety and effectiveness of medications in this population," said first author Kristina Brooks, PharmD, assistant professor of [pharmaceutical sciences](#) at the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences, located on the University of Colorado Anschutz Medical Campus.

To study the pharmacokinetics and safety of remdesivir, Brooks worked as part of the International Maternal Pediatric Adolescent AIDS Clinical Trials Network 2032 Team (IMPAACT 2032) to conduct a phase 4 open-label, nonrandomized study of over fifty hospitalized pregnant and nonpregnant women receiving intravenous remdesivir as part of clinical care.

"Given pregnant women are at higher risk of more severe COVID-19 disease and poorer pregnancy outcomes, we wanted to study whether or not the therapies given to pregnant women for COVID-19, like remdesivir, are safe and being given at appropriate doses to be effective," Brooks adds.

The researchers performed intensive pharmacokinetic sampling on days

3, 4 or 5 of remdesivir treatment and measured plasma levels of remdesivir and its major metabolites, as well as the active triphosphate form in peripheral blood mononuclear cells.

They found that remdesivir and its metabolites were at similar levels in pregnant and nonpregnant women. This suggests that no dose adjustments are necessary for remdesivir when used in pregnant women. In addition, no safety concerns were identified and they also found there were no adverse pregnancy outcomes, [maternal deaths](#) or congenital anomalies related to [remdesivir](#), though the study size was limited.

Based on these findings, the U.S. Food and Drug Administration approved a supplemental new drug application, and the European Medicines Agency granted a positive opinion supporting labeling changes from Gilead Sciences, Inc. for the use of this drug in pregnant individuals.

The study was performed within the IMPAACT Network, a global collaboration of investigators, institutions, community representatives and other partners.

"Working within an existing network of institutions was really important for getting this study done in a timely manner," said Brooks.

She concludes, "It's also important to call out that we demonstrated pharmacokinetic and safety studies can and should be performed in pregnant populations in challenging settings. This is especially important when there are emerging [infectious diseases](#) to help inform the appropriate dosing of medications in this population."

More information: Kristina M Brooks et al, Pharmacokinetics and Safety of Remdesivir in Pregnant and Nonpregnant Women With COVID-19: Results From IMPAACT 2032, *The Journal of Infectious*

Diseases (2024). [DOI: 10.1093/infdis/jiae298](https://doi.org/10.1093/infdis/jiae298)

Provided by CU Anschutz Medical Campus

Citation: New study looks at drug exposures of COVID-19 therapy for pregnant people (2024, August 13) retrieved 14 August 2024 from <https://medicalxpress.com/news/2024-08-drug-exposures-covid-therapy-pregnant.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.