

Pirfenidone reduces scar tissue in patients with heart failure

May 17 2021



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Patients with heart failure with preserved ejection fraction who took the antifibrotic drug pirfenidone saw a significant reduction in a marker of heart muscles carrying compared with patients who received a

placebo, based on findings from an early-phase trial presented at the American College of Cardiology's 70th Annual Scientific Session.

"Observational data suggests that [heart](#) muscle scarring, or fibrosis, is an important disease process for [heart failure](#) prognosis," said Chris Miller, MD, a cardiologist and National Institute for Health Research Clinician Scientist at the University of Manchester and Manchester University NHS Foundation Trust and the study's lead author. "With cardiac MRI, we were able to select a group of patients in whom fibrosis appears to be important and then reduce that scarring. While further investigation is needed, it suggests that fibrosis is an effective treatment target."

Heart failure means that the heart is no longer able to pump blood around the body properly, causing shortness of breath, swelling and fatigue. In about half of patients with heart failure, the forward pumping function of the heart, or [ejection fraction](#), is normal. This is called heart failure with preserved ejection fraction, or HFpEF. While heart failure can involve multiple factors, scarring of the heart muscle is thought to be an important contributing factor in up to two-thirds of patients with HFpEF. This new trial suggests clinicians could one day use a personalized approach to prevent or reverse scarring in those individuals, thereby slowing the progression of heart failure, Miller said.

Pirfenidone is currently approved for treating adults with idiopathic lung fibrosis, or scarring in the lungs that makes it hard to breathe. While the mechanism of action has not been fully established, the drug is thought to work by inhibiting biological processes involved in [scar formation](#). Preclinical studies suggest pirfenidone can both reduce scar tissue formation and reduce existing scarring in the heart.

Researchers enrolled patients with heart failure, an ejection fraction of 45% or higher and elevated natriuretic peptides (markers of fluid retention). Eligible patients underwent cardiac MRI scanning. Those who

had evidence of scarring in the heart muscle, as indicated by an extracellular volume (a measurement of [heart muscle](#) scarring) of 27% or greater, were randomly assigned to take pirfenidone or a placebo daily. In total, 94 patients were randomized, with 47 assigned to each treatment group.

At one year, patients underwent a second cardiac MRI to measure change in heart muscle extracellular volume, the primary endpoint. Extracellular volume declined by 1.21% on average in patients who took pirfenidone compared with those receiving placebo, a reduction Miller said was likely to be clinically significant.

"Based on the data we have from previous observational studies, this amount of change in fibrosis could translate into a significant reduction in death and hospitalization for heart failure, but further work is needed to determine this," Miller said.

The study also found evidence that fluid retention, measured using natriuretic peptides, improved in patients who took pirfenidone compared to those receiving placebo.

"The associated reduction in natriuretic peptides provides support for heart scarring having a causal role in heart failure and being an efficacious therapeutic target," Miller said. "Hopefully this work can lead to further development of therapeutics that target heart fibrosis and [scarring](#), and a phase three trial to see if pirfenidone improves patient outcomes."

The most common adverse events were nausea, insomnia and rash.

More information: Pirfenidone In Heart Failure With Preserved Ejection Fraction, American College of Cardiology 70th Annual Scientific Session, May 17, 2021

Provided by American College of Cardiology

Citation: Pirfenidone reduces scar tissue in patients with heart failure (2021, May 17) retrieved 20 June 2024 from

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