

Trial shows drug effective in 96% of patients with recurrent pericarditis

November 17 2020

Cleveland Clinic researchers leading a global clinical trial have found that rilonacept, an FDA approved drug for other inflammatory diseases, resolved acute pericarditis episodes and reduced risk of pericarditis recurrence. The study was published today in the *New England Journal of Medicine* and presented at the American Heart Association's Scientific Sessions.

Pericarditis is an inflammation of the pericardium, which is two thin layers of tissue that surround the heart and help it function. A common symptom is severe sharp chest pain, which is caused by the inflamed layers rubbing against the heart. Pericarditis can be acute, recurrent or chronic, and often occurs after a viral infection or cardiac surgery. Recurrent pericarditis usually occurs 4-6 weeks after the first episode of acute pericarditis and often causes debilitating chest pain, physical-limitations, hospitalizations and decreased quality of life.

Currently, there are no FDA approved therapies for pericarditis. Anti-inflammatories and steroids- often with harsh side effects- are used to treat the condition. The Rhapsody global Phase 3 clinical trial studied 61 patients with recurrent pericarditis, who were randomized to rilonacept or placebo. After 16 weeks of treatment, 81% of patients on once-weekly rilonacept, reported no or minimal pericarditis symptoms versus 25% on the placebo. The drug not only resolved active episodes after the first dose, but it also decreased recurrences by 96%.

All patients involved who had been taking corticosteroids tapered and



successfully transitioned to rilonacept.

"Recurring pericarditis is painful and can be debilitating to those who suffer from it," said Allan Klein M.D., director of the Center for the Diagnosis and Treatment of Pericardial Diseases at Cleveland Clinic, coprincipal investigator of the study, and a paid member of Kiniksa Pharmaceuticals' scientific advisory board. "The Rhapsody trial was highly successful, essentially stopping this disease, and provides a new hope for these patients."

Of the 25 safety events in the study, 23 occurred in the placebo group, while only two occurred in the rilonacept group.

Provided by Cleveland Clinic

Citation: Trial shows drug effective in 96% of patients with recurrent pericarditis (2020, November 17) retrieved 10 April 2024 from https://medicalxpress.com/news/2020-11-trial-drug-effective-patients-recurrent.html

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