New Clinical Trial Targets Gut Microbiota in Heart Failure

The primary outcome of GutHeart is to measure the treatment effects on left ventricle ejection fraction.

The methodology of GutHeart (ClinicalTrials.gov Identifier: [**NCT02637167**](https://clinicaltrials.gov/ct2/show/NCT02637167)), an ongoing randomized open label controlled clinical trial exploring the effect of drugs targeting the microbiota on heart failure, was published in *ESC Heart Failure*.

Most studies on inflammation in heart failure focus on downstream inflammation and tissue damage. However, GutHeart will attempt to address the gut microbiota as a potential upstream trigger of inflammatory activation. The investigators' hypothesis is that gut microbiota is altered in patients with heart failure, and microbiota in these patients contributes to inflammation. If that is taken one step further, drugs that affect the [**microbiota**](https://www.thecardiologyadvisor.com/gastroenterology-hepatology/intestinal-infections/article/597007/)may therefore have effects on either the treatment or possibly even the prevention of heart failure.

This phase 2 randomized open label controlled study is currently recruiting participants who have stable symptomatic [**heart failure**](https://www.thecardiologyadvisor.com/heart-failure/heart-failure-risk-increased-sleep-apnea-without-continuous-positive-airway-pressure/article/780832/) and are not likely to benefit from recommended treatments. Fecal samples will be taken at study inclusion, 3 months, and 6 months and analyzed to determine changes in gut microbiota populations.The primary outcome is to measure the treatment effects on left ventricle ejection fraction. Secondary end points are gut microbiota composition changes, inflammation, quality of life, functional capacity, and other cardiac parameters.

The study investigators wrote, “Our assumption is that by manipulating the bacterial composition of the gut content, we might be able to improve the inflammatory and metabolic environment for the cardiovascular system, thereby promoting cardiac healing and adaptive remodelling.”

They added, “We have chosen to test this hypothesis in a randomized controlled trial with the nonabsorbable antibiotic rifaximin, the probiotic yeast *S. boulardii*, or no treatment (control) on top of recommended treatment for heart failure.”

**Reference**

Mayerhofer C, Awoyemi A, Moscavitch S, et al. [**Design of the GutHeart — targeting gut microbiota to treat heart failure — trial: a phase II, randomized clinical trial**](https://onlinelibrary.wiley.com/doi/abs/10.1002/ehf2.12332) [published August 7 2018]. *ESC Heart Fail*. doi:10.1002/ehf2.12332