This study is a prospective randomized controlled multi-center trial. A total of 810 patients, 405 in each study arm, will be enrolled.

STUDY DESIGN

Primary Endpoint

Time to first HF event (HF rehospitalization or unscheduled outpatient visit requiring IV diuretics) within 90 days after discharge from index hospitalization.

Secondary Endpoints

- Total fluid reduced during the index hospitalization
- Total weight loss at 72 hours after randomization
- Time to freedom from congestion
- Hemodynamics at hospital discharge
- Changes in renal function variables after treatment including serum creatinine differences occurred between groups. These results indicated for extended ultrafiltration treatment of patients with fluid overload.

STUDY ENDPOINTS

This study is a prospective randomized controlled multi-center trial. A total of 810 patients, 405 in each study arm, will be enrolled.

STUDY OBJECTIVE

The primary objective is to demonstrate that patients with fluid overload treated with IV diuretics have a lower rehospitalization risk compared to patients treated with IV loop diuretics.

STUDY SITE REQUIREMENTS

- Be experienced in conducting Aquapheresis and IV loop diuretics.
- Have a comprehensive heart failure program with the resources needed to perform clinical research, including an inpatient cardiology service.
- Be experienced in conducting clinical trials.

The study is currently closed to new study sites.

STUDY PRODUCT & MATERIAL

The Aquapheresis FlexFlow™ System, which has been previously cleared by the FDA for marketing and use in the United States, is indicated for extended ultrafiltration treatment of patients with fluid overload and requires hospitalization and resource utilization for HF and is an alternative therapeutic option. The aim of AVOID-HF is to confirm and expand the findings that fluid removal by UF reduces HF rehospitalizations at 90 days as well as the length of these HF re-hospitalizations. AVOID-HF is designed with a primary end-point to determine if ultrafiltration reduces the number of HF events HF rehospitalization or unscheduled outpatient or emergency room treatment with IV loop diuretics) after discharge from index hospitalization if the patient is randomized to IV loop diuretics. AVOID-HF is going beyond the amount of fluid removal and will explore whether the modality of fluid removal influences HF outcomes.

Avocado-HF: Aquapheresis Versus Intravenous Diuretics for Hospitalization Failures

Maria Rosa Costanzo, M.D., F.A.C.C., F.A.H.A.

Midwest Heart Specialists-Advocare Medical Group, Naperville, IL

REFERENCES