

TOPCAT Trial

Trial of Aldosterone Antagonist Therapy in Adults with Preserved Ejection Fraction Congestive Heart Failure (TOPCAT).

Study Phase III

Purpose

The purpose of this study is to evaluate the effectiveness of aldosterone antagonist therapy in reducing all cause mortality in subjects who have heart failure with preserved systolic function.

The study population will include those who meet the following inclusion/exclusion criteria, some of which are:

Inclusion Criteria

- Demographics: ≥ 50 years of age.
- Signed & dated, written informed consent to participate in this study.
- Heart failure as defined by at least one of the following symptoms at the time of screening and at least one of the following signs within 12 months of study entry:

1. SYMPTOMS

- Paroxysmal nocturnal dyspnea
- Orthopnea
- Dyspnea on mild or moderate exertion

2. SIGNS

- Any rales post cough
- JVP greater ≥ 10 cm H₂O
- Lower extremity edema
- Chest x-ray demonstrating pleural effusion, pulmonary congestion, or cardiomegaly

Exclusion Criteria

- Severe systemic illness with an expected life expectancy of less than 3 years
- Chronic pulmonary disease requiring home O₂, oral steroid therapy, or hospitalization for exacerbation within 12 months of study entry, or significant chronic pulmonary disease in the opinion of the investigator
- Stroke in the past 90 days
- Gastrointestinal disorder that could interfere with study drug absorption
- Systolic BP < 160 mm Hg
- Coronary artery bypass graft surgery in the past 90 days
- MI in the past 90 days

To inquire if you are eligible for this study or hear more about it, please contact:

Pentucket Medical Associates
Clinical Trials Office
(978) 469-5494