Increasing evidence suggests that enhanced aldosterone signalling plays a key role in the onset and progression of diastolic heart failure (DHF). Aldo-DHF will test the hypothesis that aldosterone receptor blockade by spironolactone will improve exercise capacity and diastolic function in patients with DHF. Aldo-DHF is a randomized, placebo-controlled, double-blinded, two-armed, multicentre, parallel group study. Four hundred and twenty patients with DHF will be randomly assigned to receive spironolactone 25 mg per day or placebo. The main inclusion criteria are: age > or = 50 years, New York Heart Association II/III, preserved left ventricular ejection fraction (> or =50%), and echocardiographic evidence of diastolic dysfunction. The two primary endpoints are changes in exercise capacity (peak VO\(_2\), spiroergometry) and in diastolic function (E/é, echocardiography) after 12 months. Secondary endpoints include effects of spironolactone on additional parameters of exercise performance and diastolic as well as systolic function, neurohumoral activation, and quality of life. Morbidity and mortality as well as safety aspects will also be assessed. Aldo-DHF is the first
large-scale clinical trial to evaluate the effects of aldosterone receptor blockade on exercise capacity and diastolic function in patients with DHF. Aldo-DHF will provide important information about the clinical course of this condition and may have significant impact on treatment strategies and future trials in these patients.