

Pulmonary Arterial Hypertension (PAH) Clinical Trials

PROTOCOL NUMBER AC-052-414	
COMPASS 2 TRIAL	
Official Title	Effects of combination of bosentan and sildenafil versus sildenafil monotherapy on morbidity and mortality in symptomatic patients with pulmonary arterial hypertension - A multicenter, double - blind, randomized, placebo - controlled, parallel group, prospective, event driven Phase IV study
Purpose	The purpose of this study is to evaluate how safe and effective bosentan is in combination with sildenafil for the treatment of pulmonary arterial hypertension (PAH).
Investigational Drug	Bosentan
Select Inclusion Criteria	<ul style="list-style-type: none"> • Patients with the following types of PAH belonging to the WHO Group I: <ol style="list-style-type: none"> a. Idiopathic(IPAH) b. Familial PAH (FPAH) c. Associated with (APAH) <ol style="list-style-type: none"> i. Collagen Vascular Disease with normal left ventricular function(ejection fraction (EF) > 50%, ii. Congenital systemic to pulmonary shunts d. Drugs or Toxins e. PAH diagnosed by right heart catheter showing: <ol style="list-style-type: none"> i. mPAP-mean pulmonary arterial pressure ≥ 25mm Hg AND ii. PCWP- Pulmonary capillary wedge pressure (PCWP) ≤ 15 mmHg or left ventricular end diastolic pressure (LVEDP) ≤ 15 mmHg If both PCWP and LVEDP are available then the LVEDP value is retained for inclusion • Treatment with a stable dose of sildenafil equal to or greater than 20 mg three times a day (t.i.d.) for at least 12 weeks prior to randomization
Status	Open to enrollment
Contact Information	Research Coordinator: Edwinia Battle, RN, Phone: 703-776-3067, email: edwinia.battle@inova.org Principal Investigator : Steven Nathan, MD,

PROTOCOL NUMBER: TDE-PH-308	
FREEDOM-C² TRIAL	
Official Title	A 16-Week, International, Multicenter, Double-Blind, Randomized, Placebo-Controlled Comparison of the Efficacy and Safety of Oral UT-15C Sustained Release Tablets in Combination with an Endothelin Receptor Antagonist and/or a Phosphodiesterase-5 Inhibitor in Subjects with Pulmonary Arterial Hypertension
Purpose	The purpose of this study is to determine if Treprostinil diethanolamine (UT-15C sustained release) will help control the symptoms of PAH, and determine if oral remodulin is safe when it is added to other currently approved prescribed oral PAH therapies.
Investigational Drug	Treprostinil diethanolamine (UT-15C SR)
Select Inclusion Criteria	<ul style="list-style-type: none"> • Diagnosis of <ul style="list-style-type: none"> a. Symptomatic Idiopathic or Familial PAH, b. PAH associated with Collagen Vascular Disease or, c. PAH associated with HIV, with CD4 lymphocyte count ≥ 200 cells/mm³ within 30 days of Baseline and is receiving current standard of care anti-retroviral or other effective medication for treatment of HIV d. PAH associated with appetite suppressant or toxin use • Taking an approved phosphodiesterase-5 inhibitor (PDE-5), an approved endothelin receptor antagonist (ERA) or a combination of both drugs for 90 days and at the current stable dose for 30 days. • The subject has previously undergone a cardiac catheterization and been documented to have <ul style="list-style-type: none"> a. a mean pulmonary artery pressure (PAPm) > 25 mmHg, b. a pulmonary capillary wedge pressure (PCWP) or a left ventricular end diastolic pressure (LVEDP) ≤ 15 mmHg, and c. pulmonary vascular resistance (PVR) > 3 Wood units and absence of unrepaired congenital heart disease.
Status	Closed to enrollment
Contact Information	Research Coordinator: Edwinia Battle, RN, Phone: 703-776-3067, email: edwinia.battle@inova.org Principal Investigator: Steven Nathan, MD