

STUDY TITLE	RELAX-ASIA - A multicenter , randomized , double-blind , placebo-controlled phase III study to evaluate the efficacy , safety and tolerability of Serelaxin when added to standard therapy in acute heart failure patients
STUDY POPULATION	Patient admitted with Heart Failure
PRINCIPAL INVESTIGATOR	Dato' Dr. David Chew Soon Ping
STUDY COORDINATOR	Tengku Azura Tengku Saibon Contact number 03 – 2617 8200 ext 8342
START DATE	17 Aug 2014
END DATE	July 2017
INCLUSION	<p>General Inclusion :-</p> <ul style="list-style-type: none"> • Male or female subjects age 18 years or more , body weight 30kg or more and 160 kg or less • Written informed consent must be obtained before any study – specific assessment is performed • Hospitalized for AHF : <ul style="list-style-type: none"> ○ Persistent dyspnea at rest or with minimal exertion at screening and at the time randomization ○ Pulmonary congestion on CXR ○ BNP 350 pg/mL or more or NT-proBNP 1400 pg/mL or more • SBP 125 mmHg or more at the start and at the end of screening • Able to be randomized within 16 hours from presentation to the hospital, including casualty and outpatient clinic • Received IV Lasix of at least 40 mg total (or equivalent) at any time between presentation • Impaired renal functions defined as an eGFR between presentation and randomization of 25 or more and 75 ml/min/1.73m² or less calculated using the sMDRD formula • Dyspnea primarily due to non-cardiac causes such as acute or chronic respiratory • Temperature more than 38.5 or sepsis or active and clinically significant infection requiring IV antibiotic or known presence or evidence of HIV

EXCLUSION

General Exclusion :-

- Dyspnea primarily due to non-cardiac causes such as acute or chronic respiratory
- Temperature more than 38.5 or sepsis or active and clinically significant infection requiring IV antibiotic or known presence or evidence of HIV
- Clinical evidence of ACS or within 30 days prior to enrollment
- AHF due to significant arrhythmias
- Patient with hematocrit less than 25%
- COPD
- Plan for mechanical ventilation
- Hepatic disease
- Major surgery , including ICD and CRT within 30 days prior
- Any organ transplant
- Pregnant
- Subjects participating in another clinical investigation