

OPeRA-HF Study Design (Monitoring Arm): An observational study to assess and predict the in-patient course, risk of re-admission and mortality for patients hospitalised for or with heart failure

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Background: Heart failure (HF) is a common reason for hospital admission especially amongst older people. Despite the proven success of treatment many patients with a diagnosis of HF do not receive optimal management to improve their quality of life and prognosis. Few data exist on the most efficient and effective means of monitoring the in-patient course of these patients and deciding on the optimal time for discharge.

Study aims: Using a combination of the patient's social and clinical profile, daily monitoring and modelling the response to treatment, the aim is to develop objective methods to assess the patient's readiness for and barriers to discharge, adherence to management guidelines and risk of early re-admission and death. The study will also assess the practicality and utility of published discharge criteria.

Study Inclusion criteria: Age >18 years, an in-patient treated with loop diuretics and a dominant diagnosis of HF which is evident by either a left ventricular ejection fraction $\leq 40\%$ or left atrial dimension >4.0 cm or NT-ProBNP >400 pg/ml if in sinus rhythm or >1200 pg/ml if in atrial fibrillation, normally resident in the catchment area for Hull & East Yorkshire Hospitals Trust (UK) and willing and able to consent.

Data Collection: At enrolment the following information will be recorded: demo-socio-economic status, care support, clinical and family history, HF related symptoms, cognitive function, medication and devices, admission details, procedures performed (including ECG and echocardiography), sleep/mood/quality of life/symptoms and HF knowledge questionnaires, full physical examination and biophysiological tests (including bioimpedance, blood pressure, orthopnoea test), biochemistry, frailty and mobility tests. Additionally the following assessments will be made daily where practical: symptom severity, new medical problem (e.g. haemorrhage, infection, stroke, pulmonary embolism), orthopnoea testing, 50 m walk test, oedema severity, heart rate and rhythm, blood pressure (lying and standing), assessment of fluid balance by bio-impedance, blood pressure and haemodynamics by finger plethysmography, medication, investigators rating of stability, expected date of discharge, haematology & biochemistry profile. Then on the day of discharge: biochemical investigations, research bloods, HF knowledge and hospital anxiety depression scale questionnaires.

Conclusions: This study will be one of the first to make a holistic assessment of patients admitted with worsening HF, the time-course of their response to conventional treatments, the criteria for readiness for discharge and outcome.