CATSTAT-HF

Official Title of the Study:

Serum Catestatin Expression and Cardiometabolic Parameters in Patients With Congestive Heart Failure (CATSTAT-HF)

NCT number:
NCT03389386

Date of the document:

April 15th 2019

Study organizations:
University of Split School of Medicine
University Hospital of Split

STUDY PROTOCOL

Study location (site): Clinic for cardiovascular diseases, University Hospital of Split (UHSplit), Split, Croatia

Anticipated start date: Jan 2018

Anticipated end date: April 2019

Ethical Approval: This study protocol has been independently reviewed and separately approved by the Ethics Committee of the University of Split School of Medicine and the Ethics Committee of the University Hospital of Split and as such has been submitted for the registration at the Clinical Trials registry http://ClinicalTrials.gov where it was accepted and initially released on December 19th 2017.

Approval number: 2181-147-01/06/M.S.-17-2

Participant recruitment:

Participation in this study will be exclusively on a volunteer basis. Every eligible participant will receive a printed material containing information about the study and an written Informed Consent formular in Croatian language will be obtained from every subject willing to participate in the study. Participants will be divided in two groups: a) patients being diagnosed with congestive heart failure (NYHA II-IV) and b) healthy volunteers (matched controls).

Procedures:

Every patient that has received information about the study and agreed to sign the written Informed Consent in Croatian language will undergo non-invasive and pain-free procedures that will include clinical examination performed by the qualified medical doctor and/or licensed cardiologist and obtained clinical/physical examination/medical history variables will be recorded in the study formular.

Furthermore, antecubital venous blood sampling in each patient will be undertaken by the staff nurse for each participant enrolled in the study. These blood samples will then be used for the analysis of the laboratory parameters at the licensed University Hospital of Split Department

of Laboratory Diagnostics. Laboratory parameters of interest are further explained in the text below (please refer to *„Peripheral blood sampling..."* section on page 4).

- **Clinical examination will include the following:**
  - **Recording of the medical history for each participant**
  - **Basic anthropometric measurements:** age, sex, body mass, height, body mass index (BMI), neck/waist/hip circumference
  - **Determination of smoking status**: current smoker, ex smoker, non-smoker
  - **Recording of comorbidites for each patient:** diabetes mellitus, dyslipidemia, arterial hypertension, chronic obstructive pulmonary disease and/or asthma, peripheral artery disease, atrial fibrillation, valvular heart disease, coronary artery disease and other comorbidities of interest
  - **ECG records at admission and/or during index hospitalization**
  - **Recording of following clinical variables for chronic heart failure patients:** number of previous hospitalization due to heart failure decompensation (if the pariticipant was hospitalized), medical history of prior cardiac surgeries or coronary interventions, heart failure functional classification according to New York Heart Association (NYHA) graded from II to IV and all left-ventricular ejection fractions (ranging from reduced to preserved), time of heart failure diagnosis (less than 18 months or not), medical history of acute coronary syndrome (unstable angina, NSTEMI, STEMI), medical history of stroke, current medication usage (specific entries – antiarryhtmics, antihypertensives, diuretics, mineralocorticoid antagonists, digoxin, anticoagulant and/or antiplatelet therapy, special drugs such as sacubitril/valsartan or antianginals such as ivabradine, ranolazine, trimetazidine, etc.)
  - **Calculation of relevant risk stratification scores for HF patients enrolled in the study such as MAGGIC risk score, Seattle Heart Failure Model (SHFM), GWTG HF, Seattle Proportional Risk Model (SPRM) and similar <u>IN ADDITION</u>** to **CHA_2DS_2-VASc** and **HAS-BLED** scores for the subset of HF patients with a concomitant atrial fibrillation (AF)

- **Transthoracic echocardiographic (TTE) examination performed by licensed cardiologist-ultrasonographer that will examine following variables in every participant:**
  - **Left-ventricular ejection fraction (LVEF, %)**
  - **End-diastolic dimensions of left ventricle (LVEDd, mm)**
  - **End-diastolic volume of left ventricle (EDV, mL)**
  - **End-systolic volume of left ventricle (ESV, mL)**
  - **Ratio of peak flow velocity in early diastole and late diastole (E/A ratio)**
  - **Left-ventricular mass and left-ventricular mass index (LVMI)**
  - **Parameters that will be recorded in selected patients for the subset analysis**
    - **Global longitudinal strain (GLS)**
    - **Right-ventricular free wall strain (RVFW strain)**
    - **Right-ventricular systolic function**
    - **Other TTE parameters of interest**

- **Peripheral blood sampling from the antecubital vein – maximum of 22 mL will be obtained from each individual participant from both groups and following laboratory variables will be analyzed from blood samples:**
  - **Catestatin serum levels**
  - **Complete blood count, differential blood count**
  - **Coagulation panel (PT, APTT)**
  - **NT-proBNP**
  - **Cardiac hs-Troponin-I (hs-cTnI)**
  - **C-reactive Protein (CRP)**
  - **Creatinine, Urea, BUN**
  - **Electrolytes – Sodium, Potassium, Calcium, Magnesium**
  - **Lipid profile – total cholesterol, LDL-c, HDL-c, triglycerides**
  - **Other biochemical/blood parameters of interest**

CONSORT
TRANSPARENT REPORTING of TRIALS

Prospective case-controlled study – CATSTAT-HF

Conducted at the University Hospital of Split