CATSTAT-HF

Official Title of the study:

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

NCT number:
NCT03389386

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

STUDY ANALYSIS PLAN (SAP)

All data analyses will be performed by using IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY, USA) and/or Graphpad Prism 7 for Windows (GraphPad Software, Inc., La Jolla, CA, USA). All p-values in this study will be 2-tailed and results that reach $p<0.05$ will be considered statistically significant.

GENERAL STATISTICAL ANALYSES:

1. Descriptive analyses will provide data on particular categories of interest by using frequencies and percentages. Baseline sociodemographic, anthropometric and comorbidity burden data will be provided for each particular category.
2. A standard **Pearson's chi-squared test** will be used to determine statistical differences in categorical variables between the two groups of interest - congestive heart failure-CHF patients vs. healthy volunteer controls and other potential subgroups of interest.
3. The unpaired **t-test** or **Mann-Whitney U-test**, based on the data distribution normality, will be used to determine statistical differences in continuous parameters between the two groups of interest – *CHF patients vs. healthy volunteer controls* and other potential subgroups of interest, as needed. Continuous variables will be expressed as mean ± standard deviation (SD) or median ± interquartile range (IQR), based on the normality distribution.
4. **Bivariate Pearson correlation test (r)** is a parametric test that will be used to determine the significance of linear correlation between two continuous variables of interest (X, Y). In the determination of statistical correlation between continuous variables, a **multiple linear regression**, adjusted for confounders, will be used.

SPECIFIC STATISTICAL ANALYSES:

1. The **analysis of variance (ANOVA) with post-hoc Tukey HSD** test will be used to determine statistical differences in continuous parameters among the three or more subgroups of patients with CHF.
2. **Receiver operating characteristics (ROC) curve analysis** will be used to ascertain the diagnostic sensitivity and specificity as well as corresponding cut-off values of serum catestatin in determining heart failure (HF) degree and severity, e.g. *rule out, rule in.*
3. **All multivariable regression analyses** will be, at minimum, adjusted for age, sex, estimated glomerular filtration rate (eGFR), and body mass index (BMI). Other important factors such as medication intake and other potential confounding factors will be used in determining odds ratios (OR) for the disease status (congestive heart failure). Adjusted ORs, statistical significance (p) and 95% confidence intervals (95% CI) will be provided for independent predictors.

Study statistical plan is provided and revised on

April 15th 2019 by

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