

Study Title: Vascular Dysfunction in Human Obesity Hypertension: Integrative Role of Sympathetic and Renin-Angiotensin Systems

NCT: NCT01983462

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Statistical analysis plan

At baseline group differences in dependent variables between overweight/obese normotensive and hypertensive subjects and among the 3 hypertensive treatment groups at baseline (after randomization) by an independent t-test. For the main analysis, a linear mixed-model analysis for repeated measures will be used to test the effect of clonidine and HCTZ and placebo on carotid-femoral pulse wave velocity, 24 hour blood pressure, MSNA, brachial artery flow-mediated dilation. The fixed-effects in the model include time (baseline vs. 4 weeks) which is the within-subjects factor, and treatment (clonidine vs. HCTZ vs. placebo) which are the between-subjects factors in the model. The model will also include a time x treatment interaction which corresponds to testing if the mean change in each of the dependent variables after compared with before the 4 week intervention significantly differs between the groups. Bivariate correlation analyses will be performed for relations of interest between change in the dependent variables and with change in secondary outcomes (e.g. blood pressure).