

Title: Ubiquinol as a Metabolic Resuscitator in Post-Cardiac Arrest

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NCT: NCT02934555

Study overview: A single-center, prospective, double-blind, randomized, placebo-controlled phase II trial comparing oral liquid coenzyme Q10 to placebo after cardiac arrest. Consecutive adult patients who present with the following inclusion criteria and meeting none of the exclusion criteria will be approached for consent.

Inclusion criteria:

Adult (age \geq 18 years)
Cardiac arrest (in- or out-of-hospital)
Not following commands after ROSC
Ability to receive enteral medication

Exclusion criteria:

Protected populations
Current coenzyme Q10 supplementation
Anticipated death within 24 hours
> 12 hours from ROSC to randomization

Consent: The legally authorized surrogate of patients who meet all inclusion criteria and no exclusion criteria will be approached for written informed consent by members of the investigative team per standard procedures and approval from the Institutional Review Board. The study will be performed according to the Helsinki declaration.

Randomization and blinding: We will create a master randomization list stratified by the presence of shock at the time of randomization (shock defined as use of vasopressors). Patients, clinicians, and the research team will remain blinded throughout the full duration of the study.

Treatment protocol: Upon enrollment, demographic data including age, sex, race, and ethnicity, as well as vital signs and laboratory data will be recorded. A research assistant will perform venipuncture and the blood will be centrifuged and aliquoted into light-protected cryotubes and frozen at minus 80°C. After randomization and the initial blood draw, patients will be administered the study drug or placebo and will receive two daily dosages for 7 days, until hospital discharge, or until normal neurological function. Subsequent blood draws and clinical information will be collected at 24, 48 and 72 hours after the initial draw. Patients will be followed to hospital discharge for clinical outcomes.

Dosage regimen: For dose, we will be providing 300 mg of ubiquinol (active coenzyme Q10) every 12 hours. Any adverse events will be reported in real-time to the Institutional Review Board.

Outcomes: The primary outcome will be coenzyme Q10 plasma levels. Secondary outcomes will include additional biomarker measurements (including neuron specific enolase), oxygen consumption, and clinical outcomes (mortality and neurological outcomes).

Statistical analysis plan: Descriptive statistics will be used to summarize the study population. Our primary time-point of interest will be 24 hours after administration of the study drug. As a secondary analysis, we will use repeated measures linear models to analyze differences in outcomes over all time-points (0, 24, 48, and 72 hours). An appropriate variance-covariance structure will be chosen based on the Akaike Information Criteria. Right-skewed variables will be log-transformed before these analyses. All hypothesis tests will be two-sided and a p-value < 0.05 will be considered significant.