Clinical Trial Overview

Esmolol vs. Amiodarone for the Treatment of Refractory or Recurrent Out-of-Hospital Ventricular Fibrillation/Pulseless VT

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Background Information

- In murine, canine, and swine models, intra-arrest beta blockade shown to:
 - Decrease number of shocks needed to terminate VF
 - Reduce cardiac ischemia
 - Improve post-resuscitation myocardial dysfunction
 - Reduce recurrence of arrhythmias
 - Prolong survival

De Oliviera FC, et al. Resuscitation 83 (2012) 674-684

Intervention

- Randomized active-comparison of
 - Esmolol 40 mg IVP Q3-5 min as needed
 vs.
 - Amiodarone according to AHA/ECC Guidelines
- For adult OOHCA with VF/Pulseless VT refractory or recurrent following initial shock

Primary Outcome

- Neurologically-Intact (CPC 1 or 2) Survival to Hospital Discharge
- Major difficulties include:
 - Waiver of informed consent
 - Quality of other interventions (CPR, hyperventilation, etc.)
 - Post-resuscitation care variablility between hospitals
 - Decision to withdraw care not standardized

Challenges to Trial Design

- Potential differences in bioavailability of Intra-osseous vs. intravenous administration
- Post enrollment exclusions:
 - delayed presentation of DNR/Surrogate withdrawal of intensive care
- Subgroups
 - STEMI
 - Patients already on beta blockers
- Effect with respect to downtime

Pre-mortem

- Wider dose range
- Exclude CHF, renal failure, cirrhosis, metastatic cancer (the unhealthy dead)?
- Exclude very old?