

Post Traumatic Headaches (PTH): Comparative Treatment Trial

- Question: Is one treatment for PTH superior to another?
 - Prevent PTH
 - Reduce frequency and severity of PTH
 - Improve quality of life

Background

- PTH is common, disabling, and may be persistent. Occurs acutely.
- Recent data: up to 60% of TBI patients have chronic headaches persisting for up to 12 mos.
- Migraine is most common PTH phenotype
- Current practice is empiric with neurosurgeons treating with AEDs if they were trained to.
- No strong evidence from clinical trials is available to direct management
- Guidelines are empiric

Justification

- Attempt for evidence-based care
- Unclear which class of medication is superior (some data for propranolol)
- A common and disabling problem in both children and adults
- Range of treatments have include triptans, IV ergots, indomethacin, VPA, amitriptyline, topiramate, botox, & propranolol

Conceptual Approach

- Phase 3 RCT for prevention & treatment
- Adaptive design potential with different PTH therapy arms collapsing to 2 best agents
- Treat in ED after TBI diagnosed
- Age 12 and older (stratify by age)
- NO LOC or LOC < 20 min, GCS \geq 13, post-traumatic amnesia < 48 hrs, normal head CT/MRI, non-focal neurological examination

Interventions

- Randomization to daily, oral medication and subsequent titration (consider up to 4 arms):
 - propranolol
 - amitriptyline
 - indomethacin
 - topiramate
- Adaptive design to lead to 2 treatments tested
- ? Degree of blinding – single vs. double

Outcomes

- Combined frequency (headache diary) & severity (on validated pain scale) of PTH over 3 months
- Reduction in post-concussive symptoms (RPQ)
- Quality of life measures