

SCEPTER 2019

Who should be studied and how?

Goals of this panel

- Where possible, identify group recommendations/suggestions regarding the conduct of clinical trials of ICU sedation
 - For the new drug developer and the beleaguered intensivist
- NOT measurement strategies (RASS/SASS/Ramsay/PCO)
 - That's Panel 2!
- NOT outcomes (LOS, Mortality, Return to work, etc)
 - That's Panel 3!
- BUT rather
 - Structural elements
 - Inclusion/Exclusion criteria
 - Trial design

Structural elements

- Multicenter vs Single center?
 - *The committee recommends that trials of sedation...*
- Blended ICU vs single ICU type?
 - *The committee recommends that trials of sedation...*
- Wide vs narrow inclusion criteria?
 - *The committee recommends that trials of sedation...*

Inclusion / Exclusion criteria

- Age? (Dr. Shehabi)
 - *The committee recommends that trials of sedation...*
- Time to sedation? (Dr. Riker)
 - *The committee recommends that trials of sedation...*
- Control group matching (in light of so many delirium risk prediction models, should control and intervention groups be matched on all known delirium risk predictors? HbA1c, Glucose, Acidosis, Transfusion, steroid use, etc?)
 - *The committee recommends that trials of sedation...*

Trial design

- Can trials of ICU sedation be pragmatic in design?
 - *The committee recommends that trials of sedation...*
- Can trials of ICU sedation be adaptive in design?
 - *The committee recommends that trials of sedation...*
- Should trials of ICU sedation use composite outcomes?
 - *The committee recommends that trials of sedation...*
- Should trials of ICU sedation compare against a single “standard” (like propofol)
 - *The committee recommends that trials of sedation...*

Trial design

- How should trials of ICU sedation handle adjunct polypharmacy?
 - *The committee recommends that trials of sedation...*
- Should trials of ICU sedation use target controlled infusion strategies?
 - *The committee recommends that trials of sedation...*
- Should trials of ICU sedation be block randomized if possible?
 - *The committee recommends that trials of sedation...*
- Should trials of ICU sedation disclose baseline delirium and hyper/hypo rates?
 - *The committee recommends that trials of sedation...*