Clinical Trials to Evaluate Patient-Centered Outcomes of Sedation in Mechanically Ventilated Patients in the Adult ICU

March 28-29, 2019
Washington, DC
Compound Discovery

Phase 4 post marketing clinical trials

FDA Approval

Pre-clinical

Phase 1 - 3 clinical trials

WITH ALL THE ATTENTION WE GIVE YOU, YOU WON'T HAVE TO WORRY ABOUT 'MEDICAL ERRORS' OR THINGS LIKE THAT!

...BUT THIS CONSENT FORM IS FOR A PROSTATE STUDY!
Outcomes

Data Collection (GCP)

Clinical Trial Design

Practicing Clinician

FDA

Pharma

Academic Clinical Researcher

Health Care Systems

Public
Sedation Consortium on Endpoints and Procedures for Treatment, Education, and Research (SCEPTER)

• Two systematic reviews on Procedural Sedation (adult and pediatric) published

• Two consensus recommendations published on Procedural Sedation (Efficacy and Safety)

• Consensus conference on sedation for Adult ICU patients in March

• Future conference on sedation for Pediatric ICU patients

Mark R. Williams, MBBS, BSc, * Denham S. Ward, MD, PhD, †‡ Douglas Carlson, MD, §||
Who Should Provide Investigators With Direction on How to Conduct Clinical Trials of Procedural Sedation?

John F. Butterworth, IV, MD

and other stakeholders? Do either ACTTION or Williams et al \(^1\) have standing to speak for the FDA regarding what outcomes and procedures will be accepted for regulatory approval of new chemical entities? Do either ACTTION or Williams et al \(^1\) speak for the pharmaceutical industry? Do either ACTTION or Williams et al \(^1\) speak for any recognized specialty or scientific organization? Alternatively, should we regard these recommendations as well-intended advice from a group of interested investigators and consultants?

Recommendations for Procedural Sedation Clinical Trials

To the Editor

We thank Butterworth \(^1\) for his editorial that accompanies our recent article \(^2\) and helps define the different processes that are used to produce published reviews that clarify and summarize difficult clinical problems. When these reviews contain recommendations and come from regulatory or accrediting agencies (eg, Food and Drug Administration [FDA], the Joint Commission) or a professional society (eg, American Society of Anesthesiologists), they may even be considered “standards” that mandate certain clinical practices. At the other extreme are recommendations by a group of “experts,” based on evidence available in the literature, to guide clinical research investigations, including clinical trials, but not to mandate clinical practice. Our recent article, along with a related systematic review, \(^3\) falls in this latter category.
(Anesth Analg 2018;127:1146–54)

Evaluating Patient-Centered Outcomes in Clinical Trials of Procedural Sedation, Part 2
Safety: Sedation Consortium on Endpoints and Procedures for Treatment, Education, and Research Recommendations

Denham S. Ward, MD, PhD,*† Mark R. Williams, MBBS, BSc,‡ John W. Berkenbosch, MD,§

https://www.openanesthesia.org/article-of-the-month/
Healthcare Quality Domains

- Safe
- Timely
- Patient centered
- Effective
- Efficient
- Equitable
- Comfortable
- No anxiety
- No unpleasant recall
- Prompt return to baseline
- No side effects (e.g. PONV)

- Rapid recovery & D/C
- Optimal procedure outcome
- No airway intervention or CV instability

- Ease of sedation
- Consistent sedation
- Ease of procedure
- Ideal conditions for procedure
Neurologic diagnosis (e.g., head injury)

Preexisting mental impairment

Medical comorbidity

Severity of illness

Advanced age

Observable and occult metabolic abnormalities

Withdrawal from chronic psychoactive medications (e.g., benzodiazepines, opioids)

Sleep deprivation

Substance abuse or withdrawal

Noise

Sedatives

Agitation; unpleasant awareness

Elements of routine ICU care (e.g., turning, physical therapy)

Endotracheal tube

Tissue injury (e.g., surgery, trauma, pressure areas)

Pain

Vascular access

Affective component (e.g., “this pain means I’m more likely to die”)

Affect

Physical restraint

Inability to communicate

Ventilator dyssynchrony

Anxiety (appropriate or pathologic)

Frustration

Lack of homeostasis (e.g., thirst, hunger, dyspnea)

Clinical Practice Guidelines for the Prevention and Management of Pain, Agitation/Sedation, Delirium, Immobility, and Sleep Disruption in Adult Patients in the ICU

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