RESEARCH DESIGN CONSIDERATIONS FOR RANDOMIZED CLINICAL TRIALS OF SPINAL CORD STIMULATION FOR PAIN

NOVEMBER 14-16, 2018
WESTIN GEORGETOWN, WASHINGTON, DC

AGENDA

Wednesday, November 14, 2018

7:00 – 9:00 PM  Welcome Reception/Dinner
Location: Mayfair Court

Thursday, November 15, 2018

7:15-8:00 AM  Breakfast
Location: Washington Ballroom Foyer

8:00-8:15 AM  Welcome and introductions
Location: Washington Ballroom
- Richard North, MD, Simon Thomson, MD, and Dennis Turk, PhD

8:15-9:00 AM  The history of research on the mechanisms, efficacy, and safety of spinal cord stimulation
- Richard North, MD

9:00-9:45 AM  SCS clinical trial objectives and research designs, including comparison groups and testing superiority vs. non-inferiority
- Rod Taylor, PhD

9:45-10:15 AM  Sources of bias in RCTs of SCS and their mitigation
- Nathaniel Katz, MD

10:15-10:45 AM  Break

10:45-11:15 AM  Evidence standards for device approval: regulatory perspectives
- Carlos Peña, PhD (CDRH)
- Rahul Singh, MD (MHRA)
11:15 AM -12:30 PM  Group discussion: study objectives, designs, and bias
    • Moderators: Salim Hayek, MD, and Nathaniel Katz, MD
    • Panelists: Richard North, MD; Carlos Peña, PhD; Rahul Singh, MD; Rod Taylor, PhD

12:30-1:30 PM   Lunch
    Location: Mayfair Court

1:30-2:00 PM  Systematic review of methodologic characteristics and outcomes in RCTs of SCS for pain
    • Ewan McNicol, PharmD

2:00-2:30 PM  Inclusion/exclusion criteria (e.g., diagnoses, pain severity, pain duration, psychosocial vulnerabilities; treatment history, concomitant analgesics)
    • John Markman, MD

2:30-3:00 PM  Primary and secondary outcomes (e.g., pain, function, opioid sparing; duration of follow up)
    • Ali Rezai, MD

3:00-3:30 PM  Break

3:30-4:00 PM  Adverse events: assessment and reporting
    • Salim Hayek, MD

4:00-5:30 PM  Group discussion: inclusion/exclusion criteria, outcomes, and safety
    • Moderator: Nathaniel Katz, MD, and Richard North, MD
    • Panelists: Salim Hayek, MD; John Markman, MD; Ewan McNicol, PharmD; Ali Rezai, MD

7:00 – 9:00 PM  Dinner
    Location: Thomas Boardroom

Friday, November 16, 2018

7:15-8:00 AM  Breakfast
    Location: Washington Ballroom Foyer

8:00-8:30 AM  Study execution (e.g., controlling non-specific factors; programming standards; sponsor involvement; site and patient training; outcome assessment procedures)
    Location: Washington Ballroom
    • Simon Thomson, MD
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<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
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<tr>
<td>8:30-9:00 AM</td>
<td>Data analysis, interpretation, and reporting (e.g., pre-specification, estimands, missing data,</td>
<td>• Jennifer Gewandter, PhD</td>
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<td>multiplicity, clinical meaningfulness; responder definitions; “discerning hype from substance”)</td>
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<td>9:00-9:30 AM</td>
<td>Economic outcomes and cost-effectiveness analyses</td>
<td>• Brian Kopell, MD</td>
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<td>9:30-10:00 AM</td>
<td>Special issues in RCTs of SCS, including sham stimulation and programming comparisons</td>
<td>• Sam Eldabe, MD</td>
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<td>10:00-10:30 AM</td>
<td><strong>Break</strong></td>
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<tr>
<td>10:30 AM -12:00 PM</td>
<td>Group discussion: study execution, analysis, interpretation and reporting</td>
<td>• Moderator: Nathaniel Katz, MD, and Ali Rezai, MD</td>
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<td>• Panelists: Sam Eldabe, MD; Jennifer Gewandter, MD; Brian Kopell, MD;</td>
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<td>12:00-1:30 PM</td>
<td><strong>Lunch</strong></td>
<td>Location: Thomas Boardroom</td>
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<td>1:30-4:00 PM</td>
<td>Group discussion: recommendations for research methods, study execution, and reporting of RCTs</td>
<td>• Moderators: Robert Dworkin, PhD, Nathaniel Katz, MD, and Rod Taylor, PhD</td>
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<td>Location: Washington Ballroom</td>
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<td>4:00 PM -</td>
<td><strong>Departures</strong></td>
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