ESETT EEG ANCILLARY STUDY

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Outline

• Significance/Purpose
• Study Overview
• Specific Aims
• Study Equipment
  • Jordan BraiNet
  • RhythmLink Disposable PressOn™ electrodes
• Study Approach
• Challenges
• Sample Set-up and EEG
Significance/Purpose

• Emergent EEG (eEEG) would allow for early identification of SE

• Early treatment is key to avoiding pharmacoresistance

• A feasible system for eEEG in the ED could usher in a new standard of care for SE and help define a new era in SE treatment
Ancillary EEG Study Overview

• Subset of ESETT patients
• Validate ESETT primary outcome:
  • Clinical cessation of seizures
  • Important patient-oriented outcome but how prevalent are misclassification errors?
• EEG is gold standard for determining seizure cessation
  • Is eEEG practical?
  • Should it be used for all urgent patients?
• **AIM 1:** To characterize the operational parameters of obtaining an eEEG, applied by a non-EEG technologist, among patients with SE in the ED within sufficient time to evaluate immediate therapeutic outcomes.

• **This requires**
  - Trained, available non-EEG techs
  - Foolproof technical setup
  - No interference with clinical care
  - Quick data quality check
• **AIM 2:** To determine the inter-rater agreement for the presence or absence of electrographic SE, and the time of seizure cessation, from an eEEG collected within 60 minutes of enrollment in ESETT, using a rapid and quantitatively implementable scoring system on a cloud-based EEG platform.

• **This requires**
  • Consensus definition of SE
  • Quantifiable, reproducible
  • Assessable with statistics
• **Aim 3:** To characterize the concordance of clinical and electrographic outcomes in ESETT participants and to qualitatively and quantitatively describe discordant clinical scenarios
EEG Equipment/Set-up

• All equipment is FDA approved
• Jordan Neuroscience BraiNet®
  • Pediatric and adult sizes
  • Full international 10/20 system
    • 19 recording electrodes, ground and reference
EEG Equipment/Set-up

- RhythmLink Disposable PressOn™ electrodes
  - Subdermal
  - Minimize infection risk
Approach: Aim 1 Feasibility

- **Study personnel**
  - Will **NOT** have prior EEG experience
  - Standardized training: in person, video

- **Study population**
  - **Inclusion**
    - ESETT pt not at their baseline mental status
  - **Exclusion**
    - Returned to baseline mental status
    - Recent (6 months) skull defect
    - Extensive scalp infection/wound precluding electrode placement
Approach: Aim 1

- **Consent**
  - Similar to ESETT patients will be unable to provide consent
  - Anticipate either
    - surrogate consent or
    - waiver of consent initially with delayed consent to use data
Approach: Aim 1

- Timing of EEG
Approach: Aim 1

• Primary outcome: Feasibility
  • Time sensitive
    • Series of time points detailing EEG hookup process
  • Quality
    • # of electrodes dislodged
    • Signal to noise ratio of 3:1
    • Questionnaire for expert EEG reviewers
  • Interference with clinical care
    • Post-EEG questionnaire for primary nurse and physician
    • Was EEG disconnected early
Approach: Aim 2 IRR

- EEGs will be reviewed at a later date
  - Panel of 3-5 “expert” reviewers

- IRR for EEG interpretation quite variable

- Proposed Likert Scale
  1. Definite SE on EEG
  2. Likely SE (would treat further)
  3. Likely not SE (would not treat further)
  4. Definitely not SE

- Did the EEG improve over time?
Approach: Aim 2

- **Salzburg Consensus Criteria and ACNS**
  - Patients without preexisting epileptic encephalopathy
    1. Epileptiform discharges (EDs) >2.5 Hz
    2. Spatiotemporal evolution of either
       a) EDs <2.5 Hz or
       b) Rhythmic activity (≤4 Hz)
    3. Subtle ictal clinical phenomena with
       a) EDs <2.5 Hz or
       b) Rhythmic activity (≤4 Hz)
    4. If 1-3 not fulfilled, would need to document electrographic response to AEDs
Approach: Aim 3 Concordance

• Qualitatively and quantitatively describe the scenarios

<table>
<thead>
<tr>
<th>EEG</th>
<th>No electrographic seizures</th>
<th>Electrographic Seizures</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>Clinical SE cessation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ongoing SE</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Total</td>
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</table>
Challenges

• **Aim 1**
  - How many sites to involve
  - Who will be doing the EEGs at each site
  - Timing of EEG initiation
  - Assessing/determining return to baseline mental status as an exclusion criteria
  - Defining an interruption in standard clinical care

• **Aim 2**
  - Definition of electrographic seizure and SE
  - Not differentiating between seizures and SE electrographically
  - How to deal with patients with preexisting epileptic encephalopathy
  - How much can we rely on having clinical data for our definition of SE
  - Salzburg Consensus Criteria
    - “for research purposes, patient qualifies for NCSE if EEG and/or clinical improvement is documented, provided the clinical context is also in concordance with that”

• **Aim 3**
  - How valid is concordance if we are not studying the entire ESETT population
Sample Set-up