NORSE STUDY

Spring 2020 Vol. 7

COVID UPDATE: Due to the fact that patients are enrolled on a rare occasion, We will be continuing the study, including enrollment, since these participants are all inpatients, and the study procedures do not add any risk to the patients. The following modifications are to prevent research staff from any added exposure or risk. Please continue to conduct follow up visits with the following changes:

CONTENT

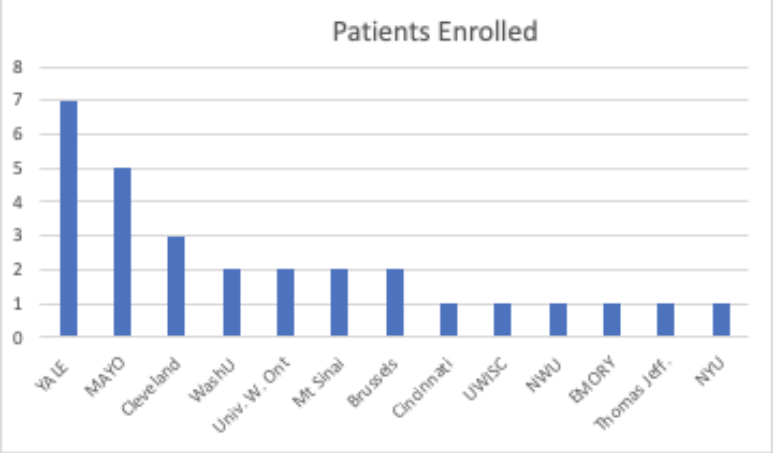
-Replacing in-person study visits with remote options utilizing telemedicine (or regular phone)

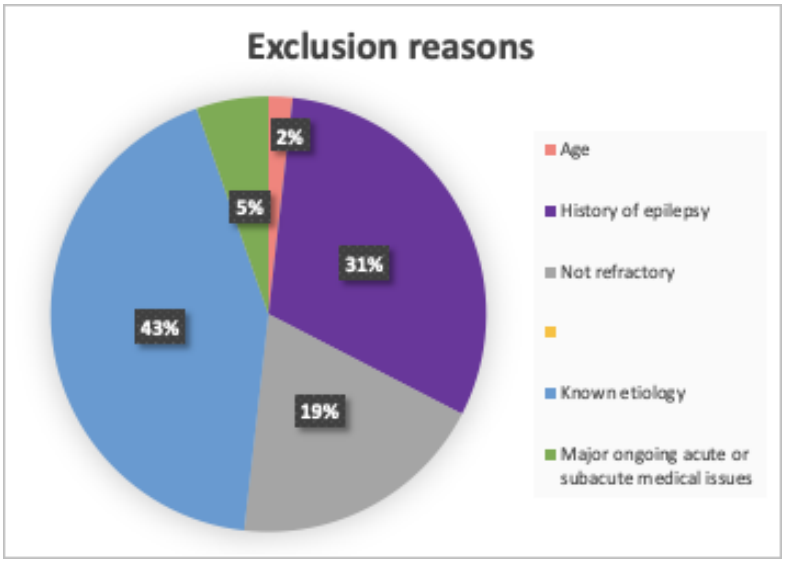
-Do not allow research staff to come to hospital for consent, enrollment, or any other procedures until the acute portion of the pandemic is over. All activities should be done remotely.

At this time, we will not be sending or receiving any specimen kits, tubes, labels, or any other supplies.

Please check with your institutional rules and IRB if you are required to submit these updates to your IRB.If you are conducting a modification, please notify the Study Coordinator and the PI's.

Enrollment & Screening Updates





Since Nov 2018, we've screened 584 cases.

- We have 25 IRB approved sites, 11 sites pending approval.
- 29 patients enrolled. Goal = 100
  - Top enrollers: YALE & MAYO

Patient Information

- **24% Male, 76% Female**
- **Age range 6-83**
- **Average length hospital stay: ~30 days**
- **2 pediatric: 6 & 9 y.o**
- **55% QUALIFY as FIRES (incl. both peds cases)**

7 Patients deceased. 5 OF 22 reached 6 mo. f/u. 4 of 5 had good outcome (GOSE 5 or higher). With very good outcome in 3 of 4 that reached 12 mo. f/u

Treatment

- Immune therapy was given to 15/21 patients, beginning at a median of 4.5 days (range 0-23) after RSE onset
  - Including Steroids (14 patients)
  - IVIG (8 patients)
  - Plasmapheresis (9 patients)
  - Tocilizumab (1 patient)
  - Rituximab (1 patient)

Biorepository

- **SERUM: collected from 26 pts**
  - **Average cc: 9.1 per pt**
- **Whole Blood: 25 pts**
  - **Average cc: ~6 per pt**
- **CSF: 21 pts**
  - **Average cc: ~6 per pt**
- **Brain samples from 3 pts**

Goals & Reminders

Upcoming Goals

- Finish all IRB applications & contract negotiations
- **Increase Enrollment, GOAL = 100**
- **Complete ALL follow up visits**
- **Collect all data in redcap**

Reminders

- Patients may be able to be enrolled if status has resolved if the case was initially overlooked and the patient is still in your hospital; please check with us if this occurs rather than not enrolling at all
- All NORSE/FIRES cases should be enrolled, even if the presumed cause was identified after the first 24 hours
- Children w. cognitive delay can be enrolled if no prior sz
- Contact Abiha if you have expired supplies, please check your kits!
- Brain samples can be collected (if autopsy or biopsy conducted)

REDCAP

- Would you like assistance entering data in redcap? We can help with data entry. Contact Abiha!
- If a new study team member/research assistant is added, please inform the study coordinator to provide a netid for redcap access.
- Collection of daily data must be completed for 6 weeks or until pt is discharged *Data doesn't have to be entered everyday, but can be entered retroactively.

Authorship Policy

- For enrolling 1 patient: up to 2 authors/center
- For enrolling 2-5 patients: up to 3 authors/center
- For enrolling 6 or more patients: up to 4 authors/center

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