Thoracostomy Tube Irrigation: A Multi-Center Trial Investigating its Efficacy in the Reduction of Secondary Intervention for the Management of Retained Hemothorax

Coordinating Site Protocol

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Site Information:

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Participating Sites:

Exact participating sites are being determined on an on-going basis. This study is being hosted by the Multi-Center Trial Committee of the Western Trauma Association (WTA). Once the exact sites are determined, we will create a listing of all sites where data will be collected, including the name and CV for the lead investigator at each site. This listing will be provided to both the Medical College of Wisconsin (MCW) IRB and all participating sites.

It will be expected that each participating site will submit this study to their own IRB for review. All IRB approval letters will be collected by the lead site. We will not be submitting a reliance agreement.

The same study protocol will be disseminated to all participating sites. We anticipate some variability in the standard of care of thoracic irrigation at participating sites. At MCW, thoracic irrigation is standard of care, so we will be requesting a waiver of consent. Participating centers where this is not the case may need to obtain consent.

There will be no minimum or maximum number of patients enrolled at each site. The methods, power analysis, and sample size are discussed in more detail in the separate study protocol. There will be an interim analysis, and once an adequate number of patients has been collected based on our current power analysis, no further patients will be enrolled at each site.

Coordinating Site Leadership Structure:

MCW principal investigator is responsible for the guiding and overseeing of all phases of this multi-center research study. Other approved MCW study staff will assist with organization and communication, including research fellows, surgery residents, and surgery department research coordinators. MCW will provide the administrative, clinical, technical expertise, and leadership in the design and coordination of this multi-center research project. MCW PI will be responsible for data monitoring for accuracy and integrity, subject screening & enrollment, data and safety monitoring, data collection and analysis, adherence to the protocol-directed procedures and guidelines, and the prompt review, reporting, and resolution of adverse events. Lead investigators at the participating sites will submit this study for review by their local IRB. MCW as lead site will maintain records of IRB reviews and approval for all participating sites throughout the duration of the study.

Coordinating Center's Responsibilities:

All participating sites will be provided with the most current version of the study protocol. If any changes are made, the updated protocol will promptly be disseminated to all sites via email. We will obtain IRB approval documentation from all participating sites. Any IRB approved modification to the study protocol will be communicated in writing to all participating sites.

In the startup phase, there will be communications as needed with participating sites to assist with IRB submission and study initiation. These communications will be email, with conference call options pending availability and interest of participants. Once all IRBs have been approved and study enrollment has begun, monthly communications via email or phone will be conducted with the study staff at all participating sites to ensure continued compliance with the protocol. All sites will conduct the study according to established IRB protocol. All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy and reported to MCW. All participating sites will safeguard data as required by local information security policies.

MCW PI bears the ultimate responsibility for safeguarding the rights and welfare of humans participating in the study.

Project Timeline:

- January 1st, 2021: IRB approval at all participating sites
- December 31st, 2022: Data collection completed
- July 1st, 2022: Data analysis completed

Sample Protocol & Data Collection Tools:

The most current version of the study protocol will be provided to all participating sites. If any changes are made to the study protocol, a new version will promptly be disseminated to all sites. This study protocol will be submitted to each collaborating institution for review and approval by their IRB committee. Each site will also be provided with a data collection tool and data dictionary, which includes a list of all variables to be collected as well as a definition of each variable.

Data Transmission, Storage, Analysis:
Data storage at MCW:

Only approved study staff will have access to the data in question and to patient protected health information (PHI), which will be used to determine eligibility. All collected PHI will be kept in a locked filing cabinet in the locked office of study staff when not in use. Data will be entered into a secure password protected electronic excel spreadsheet, with all electronic data stored on the secure MCW Box platform.

The MCW Box platform is a secure data storage system provided through the Medical College of Wisconsin. The MCW Box platform provides data encryption utilizing 256-bit SSL, SSAE 16 Type II, and maintains a safe-harbor certification for security. Box sync's encrypted authorization token technology keeps user data secure and work seamlessly with existing MCW desktop encryption systems.

MCW Box is licensed for storage of PHI data as it provides maximum security and allows users to assign different levels of security based on individuals' roles within a project. All files stored on MCW Box are stored within a secure server on the MCW campus and can be synced to MCW owned computers kept in locked offices within Froedtert Hospital.

Content from Box is available remotely through their encrypted website which requires two step verification and login each time the site is accessed. Users have access only to files in which they have been granted access, increasing the security of data storage.

Data storage at participating sites:

Only approved study staff will have access to the data in question and to PHI, which will be used to determine eligibility. The lead investigator at each participating site will be responsible for storing data according to their institutional security policy.

Data Transmission:

Data will be collected at each participating site and entered by a member of the study team into a REDCap database created for this project. Only approved study staff will have access to the REDCap database. All data entered in REDCap will be deidentified.

Data Analysis:

No patient identifiers will be included in the REDCap database. All data analysis will take place at MCW in conjunction with MCW biostatisticians. There will be an interim analysis once 50% of patients have been enrolled in the experimental arm, and any changes to sample size will be made at that time. Any changes to protocol or sample size will be communicated to all participating sites. Final data analysis will be conducted at MCW once all patients have been recruited in the propensity score matched design.

Central Data & Safety Monitoring Plan:

In the startup phase, there will be communications as needed with participating sites to assist with IRB submission and study initiation. These communications will be email, with conference call options pending availability and interest of participants. Once all IRBs have been approved and study enrollment has begun, monthly communications via email or phone will be conducted with the study staff at all participating sites to ensure continued compliance with the protocol and discuss any adverse events. All participating sites will safeguard data as required by their local information security policies. The lead investigator at each participating site will be responsible for data storage according to institutional policy. All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy and reported to the PI at MCW. Data will be collected from all participating sites using a deidentified REDCap database created for this project.