jolt-ca

Joint Lung Cancer Trialist's Coalition

Newsletter for Clinical Trial Partners / May 2019

A Randomized Phase III Study of Sublobar Resection (SR) versus Stereotactic Ablative Radiotherapy (SAbR) in High-Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC)

STABLEMATES TRIAL

TIPS:

- *Follow-up procedures*: If patients only agree to the follow-up portion of the study, the study calendar should still be followed (section 9.5) with all procedures listed at the designated timepoints being completed by someone on the study team delegated to perform the procedures.
- There is a video on the **JoLT-Ca website** that can be used to explain the trial to patients. A transcript of the video can be found in Appendix E of the protocol.
- Remember to upload eligibility checklist and consent within two business days of completion. Treatment and follow-up information should be entered within 30 days of the visit/end of treatment.
- If new personnel are going to be added to a subsite's study team, please notify Sarah Hardee Neufeld so she is aware.
- If errors need to be corrected, ensure that the corrections are initialed and dated.
- If a patient has an SAE (Section 11.4), fill out the SAE form on the Jolt website and submit to Sarah. All deaths need to be reported regardless of relatedness. If there are questions about whether or not something needs to be reported, please contact Sarah.
- Make sure the eligibility checklist is signed off by the appropriate parties to meet the criteria.
- Do not contact IROC for credentialing documentation. Instead, visit the Stablemates website at **www.joltca.org**.
- **A patient's eligibility must be confirmed prior to randomization, which includes having source documents for the eligibility criteria as well as a signed and dated eligibility checklist available for after the patient consents to the trial.**
- **Study procedures must be done per the protocol schedule (study calendar in section 9.5). If anything is missed or not completed, the deviation needs to be completed.**
- **If a waiver is needed for a patient (eligibility or a protocol assessment cannot be completed), please contact Sarah who will provide the form that needs to be completed and returned. Once it has been reviewed by UTSW, and if the waiver is approved, the form will be returned to the site for submission to their IRB.**

Sarah Hardee Neufeld can be reached at Sarah.Hardee@utsw.edu or 214-648-1836.

Sabrina Chowdhury will be in contact with some sites regarding missing data fields. Please be sure to respond to her emails as soon as possible.

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Jolt-Ca Study Accrual by Site

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New site activation: Clement J. Zablocki VA Medical Center, PI: Elizabeth Gore

SUBSITE UPDATE

Active:

- Anne Arundel Medical Center
- Boston University
- Cardiothoracic and Vascular Surgeons - Austin
- Case Western
- CHUM-Notre Dame Hospital
- Clement J. Zablocki VA Medical Center
- Cleveland Clinic
- Henry Ford Health System
- INOVA
- Intermountain Medical Center
- Lifespan Oncology Clinical Research
- Medical College of Wisconsin
- Memorial Health University
- Meridian Health
- New York University
- Ochsner Medical Center
- Ohio State University
- Ottawa
- Penn State (Mount Nittany Medical Center)
- Penrose Cancer Center
- Providence Health and Services
- St. Vincent's – Australia
- SUNY
- Swedish Cancer Institute
- Thomas Jefferson University
- University of California San Diego
- UHN - Toronto General Hospital
- University of Cincinnati
- University of Colorado/Memorial
- University of Iowa
- University of Kansas
- University of Louisville Physicians
- University of North Carolina Chapel Hill
- University of Pittsburgh Medical Center
- UT Southwestern Medical Center
- University of Virginia
- West Clinic/University of Tennessee
- William Beaumont Hospital

Completed contracts:

- Sunnybrook

Completed IRB approval:

- CERV

If there are any questions regarding how to enter data-screen patients or any other aspect of the trial, please email or call Sarah.

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