jolt-ca

Joint Lung Cancer Trialist's Coalition

Newsletter for Clinical Trial Partners / January 2019

UTSouthwestern
Harold C. Simmons
Comprehensive Cancer Center
Radiation Oncology

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

Crisis of Acceptance:

The Stablemates protocol design made assumptions about the acceptance rate of the pre-randomization assignment based on the older NSABP breast trial (using the same design) where 90% of women accepted the assignment. The acceptance rate is important for determining the overall sample size for the trial, which subsequently determines important budget issues (e.g. site reimbursement for accrual). We "conservatively" assumed the Stablemates acceptance rate would be 80%. Much to our dismay, it is currently only 54% for the 145 patients that have been randomized. This has several sobering consequences, including a likely need to increase the sample size as well as problems meeting budget.

The pre-randomization design attempts to allow patients a prominent role in decision-making that affects their care. That's a noble and reasonable construct. Ideally, though, patients would accept according to study design, which is more likely in the following circumstances:

1. The patient is knowledgeable about the standard of care (i.e. surgery) and the experimental therapy (i.e. SAbR) and objectives
2. The patient is knowledgeable about the study procedures, and
3. Importantly, the patient and providers have equipoise.

The first two require a consultation providing understandable description of the disease status and requirements for cure. Both the surgery and SAbR must be described in fair context including their historical use and performance. The third point means that the patient understands that a "best" treatment cannot be clearly defined without the results of a randomized trial. The provider has to confess a lack of insight into this as well, otherwise provider bias will creep toward the patient.

We have a **Stablemates video**, IRB-approved for all sites, on the JoLT-Ca website that tries to address all three points. We're not sure sites are using this video when seeing patients, but believe it could be helpful to improve the acceptance rate.

Sites with higher acceptance rates tell us that they discuss the trial with the patients prior to randomization. Again, the patient always maintains the right to refuse the assignment. However, patients who are aware of the trial in advance and, ideally, have expressed a willingness to accept either assignment (surgery or SAbR) prior to randomization will most likely accept the assignment after randomization. This is a reasonable compromise helping patients understand how they can help us better understand how the two treatments will eventually be best utilized after the trial is completed and published.

The strategy that DOESN'T work is to randomize the patient hoping for a favored treatment, planning a priori to reject if the verdict is not favored. In this scenario, our acceptance rate will hover around 50% which makes the trial untenable.

We hope to improve the acceptance rate in the upcoming months away from "crisis" levels. We appreciate your help and willingness to accrue to Stablemates using this more novel trial design at your center.

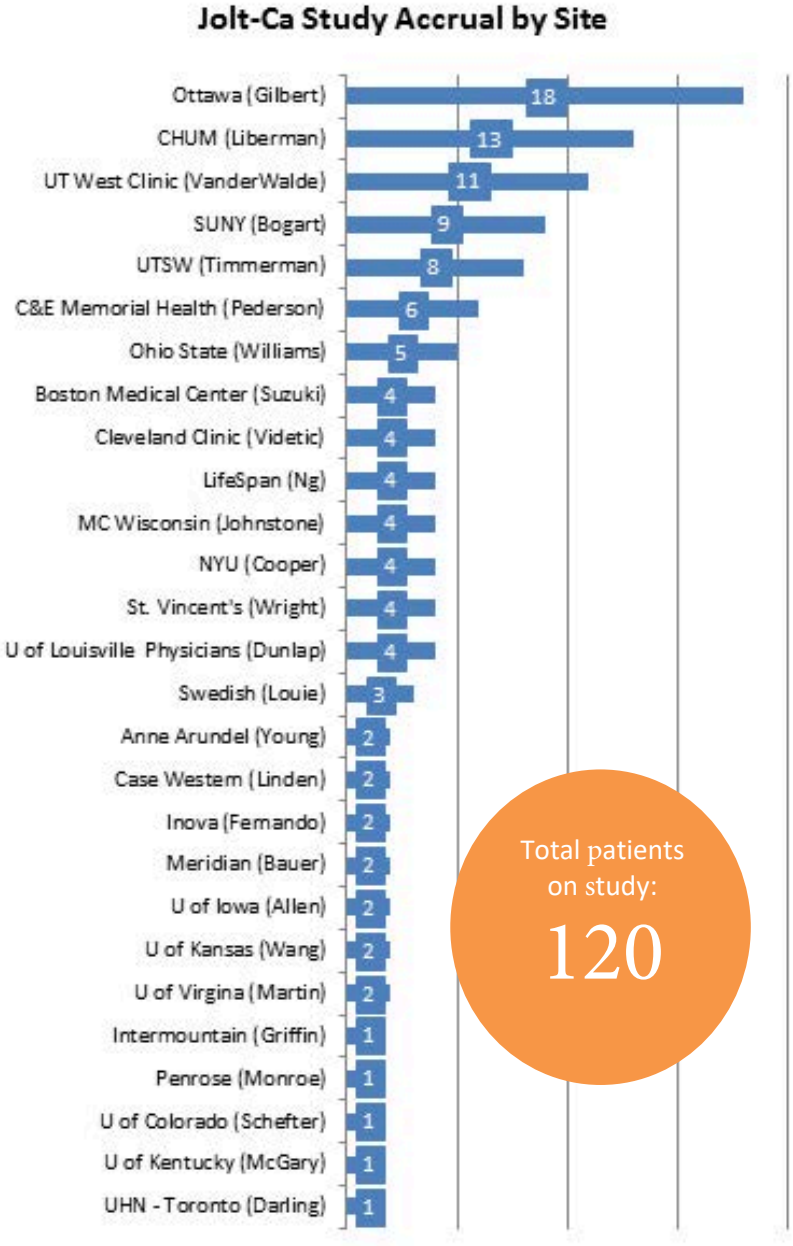
jolt-ca

Joint Lung Cancer Trialist's Coalition

Newsletter for Clinical Trial Partners / January 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**.

jolt-ca

Joint Lung Cancer Trialist's Coalition

Newsletter for Clinical Trial Partners / January 2019

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.

Study Co-Chair & Surgery QA Study — Hiran Fernando, MD | hiran.fernando@inova.org | 703.776.3563
Co-Chair & Radiation QA — Robert Timmerman, MD | robert.timmerman@utsw.edu | 214.645.7651
Statistician — Chul Ahn, PhD | chul.ahn@utsw.edu | 214.648.9418
Management Analyst — Sarah Hardee Neufeld, MS | sarah.hardee@utsw.edu | 214.648.1836
Research Manager — Sarmistha Sen, MS, MHA | sarmistha.sen@utsw.edu | 214.645.1477