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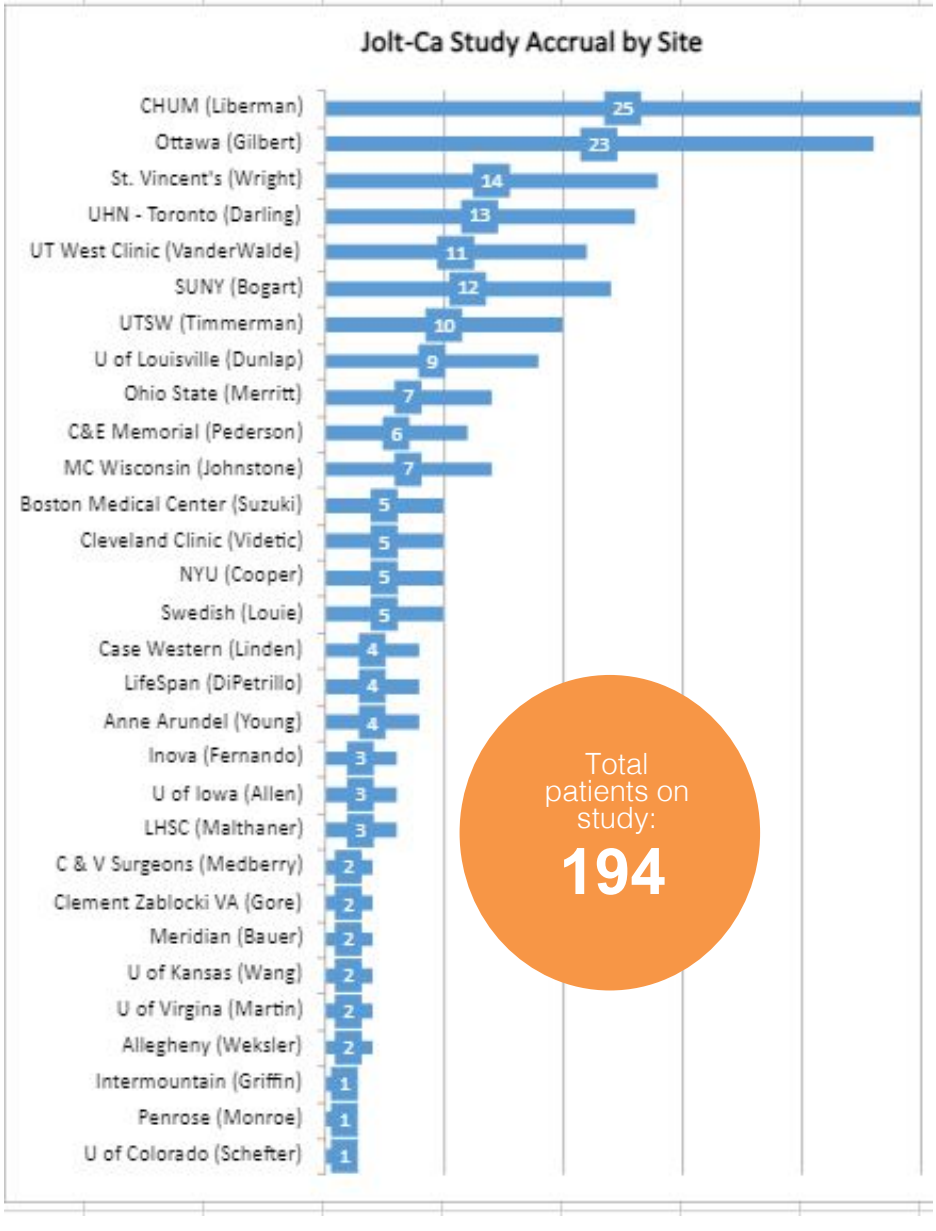
Joint Lung Cancer Trialist's Coalition

Newsletter for Clinical Trial Partners / November 2021

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



Recent Patient Enrollment

Medical College of Wisconsin

PI: *Dr. David Johnstone*
Surgeon: *Dr. Mario Gasparri*
Radiation Oncologist: *Dr. Lindsay Puckett*
Coordinator: *Madiha Arshad*

Allegheny

PI: Dr. Benny Weskler
Radiation Oncologist: Dr. Athanasios Colonias
Coordinator: Emily Smith

Please remember: Use the eligibility criteria from the v5 JoLT protocol/REDCap eligibility form (printed in real time) as the eligibility checklist before randomizing a patient.

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Please ensure all **current regulatory documents** have been submitted for review.

SUBSITE UPDATE

Active:

- Allegheny
- 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
- Elizabeth Anderson Cancer Institute at Memorial University
- Lifespan Oncology Clinical Research
- London Health Sciences Center
- Medical College of Wisconsin
- Meridian Health
- New York University
- Ohio State University
- Ottawa
- St Vincent's – Australia
- SUNY
- Sunnybrook Health Sciences Centre
- Swedish Cancer Institute
- Trillium Health Partners
- UHN - Toronto General Hospital
- University of Colorado/Memorial
- University of Iowa
- University of Kansas
- University of Louisville Physicians
- University of Pittsburgh Medical Center
- UT Southwestern Medical Center
- University of Virginia
- West Clinic/University of Tennessee

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

Study Co-Chair & Surgery QA Study	Hiran Fernando, M.D. | hiran.fernando@ahn.org | 703.776.3563
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Research Study Coordinator	Vaidehi Chemburkar, MS | vaidehi.chemburkar@utsw.edu

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Cheat sheet* for randomizing and enrolling a patient to the JoLT-Ca Stablemates trial.

a. Print the inclusion criteria from version 5.0 JoLT-Ca Protocol (section 3.1, pages 8, 9 and 10) to use as the eligibility checklist, which would be best practice.

- Printing the REDCap eligibility form is an alternative. If you choose to do this, please remember to print it in real time.
- Please mark "yes" or "no" beside every inclusion criteria on the checklist and make sure that they match your selections in REDCap (eligibility form). The data entered in REDCap should always match the eligibility checklist being used as source.

b. Things you need prior to randomizing a patient:

- The eligibility checklist needs to be signed and dated by the physician prior to randomization. If the signature is wet, we require a wet date beside it. If the signature is digital, then we require a digital summary.
- ECOG score needs to be documented in a physician note from before the date of randomization. If this has not been documented, please have the physician write the score on the eligibility checklist near criteria 3.1.2 and have them initial and date beside it before randomizing the patient.
- Biopsy/path report within 180 days prior to randomization.
- PET/CT scan of the chest and upper abdomen within 180 days prior to randomization.
- Inclusion criteria 3.1.7 and 3.1.8 (tumor verified by a thoracic surgeon to be in a location that will permit sublobar resection and tumor located peripherally within the lung) needs to be documented in the surgery consult note by the physician. A surgery consult note is mandatory.
- PFT within 180 days prior to registration.
- Inclusion criteria 3.1.15 – women of childbearing potential must have a negative pregnancy test. For older women, we need a source for their post-menopausal status/hysterectomy, which can be an H&P report or an NTF signed from before the date of randomization.

c. Randomize the patient (page 41, section 13.4.2) – upload the signed eligibility checklist to REDCap.

d. Consent the patient – please upload all the baseline data collected to confirm eligibility to REDCap within 5 days of consent including the ICF and consent process note. Remember to include documentation of randomization acceptance or rejection, and if they agree to be followed on the study in the consent process note.

**Cheat sheet to be used only as a supplement to the study calendar (page 28) and protocol.*

9.5 Study Calendar[12]

Tests and Observations	Within 60 days prior to randomization. (except where noted)	After reg. and before SAbR or surgery	Both arms (From date of surgery/end of SAbR) [±2 weeks window on each time point][5]									Every 6 mo. thereafter until 60 mo.[6]	At time of disease relapse / PD[13]
			4 weeks	3 mo.[11]	6 mo.	9 mo.[11]	12 mo.	15 mo.[11]	18 mo.	21 mo.[11]	24 mo.		
History & Physical, ECOG/Zubrod PS	X		X	X	X	X	X	X	X	X	X	X[7]	X
Pregnancy test (urine or serum)	X[1]												
Tumor biopsy (required) and LN biopsy (if needed)	X[9]												X[3b]
Pulmonary Function Tests	X[8]			X	X		X				X		
PET/CT scan chest/upper abdomen	X[10]				X[3a]		X[3a]				X[3a]		X[3a]
CT scan chest/upper abdomen				X		X		X	X	X		X	X
Adverse event assessment	X	X	X	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]	X[4]		X[4]
Charlson Comorbidity Index		X											
LCSS[14]		X	X	X	X		X				X	X	
QA submission to JoLT-CA Radiotherapy QA Headquarters		X[2]	X										

1 - For patients of childbearing potential.
2 - Submission to JoLT-CA Radiotherapy Headquarters of the first radiation (randomized to RT and accepted the randomization) patient's treatment plan prior to treatment for each site unless waived (per 6.6.4). Otherwise the treatment plan needs to be submitted after RT is completed.
3a - During post-treatment follow-up, CT scan may be substituted for PET/CT if PET/CT will not be reimbursed by the patient's insurance. The reason for each deviation from the protocol must be documented in patient records.
3b - In any instance a CT alone is suspicious for relapse/progression; biopsy of relapse/progression sites is highly recommended but not required. However, if biopsy is not performed, PET/CT must be performed to confirm disease. Submission of biopsy pathology report (if applicable) and scan reports is required. After disease relapse/progression or development of a secondary primary, patients will be followed for survival status as required by the study calendar. Adverse events will be followed.
4 - Adverse event assessments are required for all patients during the first 24 months after completion of protocol therapy, unless disease relapse/progression happens prior to the 24-month time point.
5 - Arm 1 patients (surgery) with benign disease on final pathology will be followed for survival status.
6 - It is highly recommended that patient should be followed every 6 months after month 24 (at month 30, 36, 42, 48, 54, 60) for 5 years. A minimum of annual follow-up is required. Any additional studies may be performed at the treating physician's discretion as needed.
7 - Patients who refuse to accept randomization but consent to be observed need to be followed as per point 6 above. Any additional studies may be performed at the treating physician's discretion.
8 - Baseline PFTs are required within 180 days prior to randomization. PFTs must include routine spirometry and DLCO. Arterial blood gases are not required but may be used as minor criteria for study enrollment. See eligibility criteria.
9 - Tumor biopsy is required within 180 days prior to randomization.
10 - PET/CT scan is required within 180 days prior to randomization.
11 - It is highly recommended to follow up with patient every three months for the first 24 months. Patient will be followed at least every 6 months in any circumstance during the first 2 years.
12 - If a given patient's health care payer refuses payment for any study evaluation, that evaluation may be omitted. However, documentation of this refusal must be available.
13 - See section 9.2.
14 - Lung cancer symptom scale.