jolt-ca | Joint Lung Cancer Trialist's Coalition

UT Southwestern Medical Center

Newsletter for Clinical Trial Partners

Summer 2015, Issue 1

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"

Welcome to the first e-newsletter for the Stablemates Trial, a study meant to finally directly compare surgery and stereotactic radiation in the treatment of early stage lung cancer.

Following the failure of a similar previous attempt to competitively assess these two "workhorses" of cancer treatment due to lack of accrual, this trial utilizes a novel prerandomization method to encourage patient participation. Patients are informed at the outset of their prerandomization assignment and thus can more actively participate in the management of their care.

This strategy is borrowed directly from the paradigm-changing trial NSABP B-06 comparing mastectomy vs. lumpectomy, which was instrumental in radically changing the standard of care for breast cancer.

Our earlier studies investigating SAbR for early stage NSCLC in inoperable patients resulted in many patients who were previously ineligible for treatment of any kind not only receiving treatment but being cured. This has been very gratifying.

With a success rate seemingly competitive with surgery, the next logical step is to explore this noninvasive treatment as an alternative to surgery in high-risk but still operable patients, where lobectomy is not considered to be a good option. Both surgery and SAbR are evolving to produce better results, and the Stablemates Trial will help find the best place for each therapy.

Over the next few months, we hope to open this trial in 30-40 sites in the U.S. and Canada, with UT Southwestern as the national organizing center, statistical center, and data safety monitoring center. As a reminder:

- All sites will receive startup fee reimbursement and $6,500 per patient accepting randomization. For patients rejecting randomization but allowing follow-up of standard treatment, $3,000 will be provided.
- If the Stablemates Trial is successful, the industry-funded JoLT-Ca structure may provide a viable opportunity for future "surgery or radiation" trials difficult to fund in government cooperative groups.

Study co-chairs Hiran Fernando, M.D., and Robert Timmerman, M.D.

We thank those partners who share our vision of providing more advanced care to individuals suffering from cancer, and we look forward to working with you in the days to come.

Why "Stablemates"?

The therapies (surgery and SAbR) are both fiercely competitive, like thoroughbreds in a race. Yet when not competing on the track, they reside together in a stable enjoying each other's company – ready and eager to be called on for the next challenge.

Study Co-Chair & Surgery QA ..... Hiran Fernando, MD | hiran.fernando@bmc.org | 617-638-5600
Study 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
Research Manager ..... Jean Wu, RN, MSN, OCN | jean.wu@utsw.edu | 214.648.1892
Budget & Contracts ..... Margie Harper | margarette.harper@utsw.edu | 214.648.8038
Newsletter ..... Dee Hill | dee.hill@utsw.edu | 214.645.7650

Committed partners*

* Credentialed sites that have submitted the participation questionnaire

- Allegheny General Hospital
  Pittsburgh, PA
- Boston Medical Center
  Boston, MA
- CHUM - Notre Dame Hospital
  Montreal, Canada
- City of Hope
  Duarte, CA
- Curtis & Elizabeth Anderson Cancer Institute at Memorial University Medical Center
  Savannah, GA
- Henry Ford Health System
  Detroit, MI
- Intermountain Medical Center
  Murray, UT
- London Health Sciences Centre
  London, Ontario, Canada
- Mayo Clinic Rochester
  Rochester, MN
- Ochsner Medical Center
  Jefferson, LA
- The Ohio State University Wexner Medical Center
  Columbus, OH
- The Ottawa Hospital
  Ottawa, Ontario, Canada
- Providence Health & Services
  Portland, OR
- Rhode Island Hospital
  Providence RI
- University of California San Francisco Medical Center
  San Francisco, CA
- University of Chicago Medicine
  Chicago, IL
- University of Kentucky Health Care
  Lexington, KY
- University of Louisville Physicians
  Louisville, KY
- University of Maryland Medical Center
  Baltimore, MD
- University of Texas Southwestern Medical Center
  Dallas, TX
- University of Virginia Health System
  Charlottesville, VA

Executive committee

Hiran Fernando, M.D. (Boston U)
Robert Timmerman, M.D. (UTSW)
Chul Ahn, Ph.D. (UTSW)
Hak Choy, M.D. (UTSW)
Shanda Blackman, M.D. (Mayo)
Robert Cerfolio, M.D., MBA (UAB)
Traves Crabtree, M.D. (Washington U)
Gail Darling, M.D., FRCSC, FACS (U Toronto)
Rodney Landreneau, M.D. (Allegheny)
Robert McKenna, M.D. (Cedars-Sinai)
Jeff Bradley, M.D. (Washington U)
Ken Olivier, M.D. (Mayo)

Key eligibility

- ★ Biopsy confirmed non-small cell lung cancer
- ★ Tumor ≤ 4 cm maximum diameter
- ★ Tumor located peripherally within the lung (not touching any surface within 2 cm of the proximal bronchial tree in all directions). Patients with non-peripheral (central) tumors are NOT eligible.
- ★ No evidence of distant metastases
- ★ High risk for lobectomy (e.g. FEV1 ≤ 50%) but likely able to tolerate sublobar resection.

Protocol amendments

- ★ Inclusion of the recent combined analysis of the STARS and ROSEL randomized trials comparing SAbR vs. surgical resection, which found significantly improved survival with SAbR, further reinforcing the need for successful completion of a randomized trial comparing the two treatment modalities as well as providing justification for the design of Stablemates as a superiority trial.
- ★ Plan for continued evaluation of patterns of failure and overall survival until 5 years as secondary endpoints.
- ★ Updated inclusion criteria to include patients with radiographic findings of ground-glass opacities with > 50% solid component.