

UTSouthwesternMedical Center

Newsletter for Clinical Trial Partners

November 2016

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"

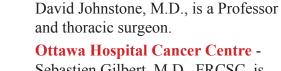
Five more sites activate with Stablemates

New sites that are ready to enroll patients include:

Boston University - The team is led by Hiran Fernando, M.D., who also serves as the Stablemates study chair and director of surgery QA. Dr. Fernando is Professor and Chief of Thoracic Surgery, and Director of the Center for Thoracic Oncology.

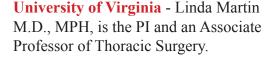
Intermountain Medical Center - David Griffin, M.D., a cardiovascular & thoracic surgeon, is the PI.





Ottawa Hospital Cancer Centre -Sebastien Gilbert, M.D., FRCSC, is the PI. He is an Associate Professor of Surgery and Director of the Minimally Invasive Aerodigestive Surgery Program of the Ottawa Hospital.

Medical College of Wisconsin - PI









Subsite update

Active

- Anne Arundel Medical Center
- Boston University
- CHUM-Notre Dame Hospital
- Henry Ford Health System
- Intermountain Medical Center
- Lifespan Oncology Clinical Research
- Medical College of Wisconsin
- Memorial Health University
- Ochsner Medical Center
- Ohio State University
- Ottawa

- Penn State (Mount Nittany Medical Center)
- Penrose Cancer Center
- SUNY
- Swedish Cancer Institute
- University of Kentucky
- University of Louisville Physicians
- University of Maryland
- UT Southwestern Medical Center
- University of Virginia
- West Clinic / University of Tennessee

Completed contracts and IRB approval:

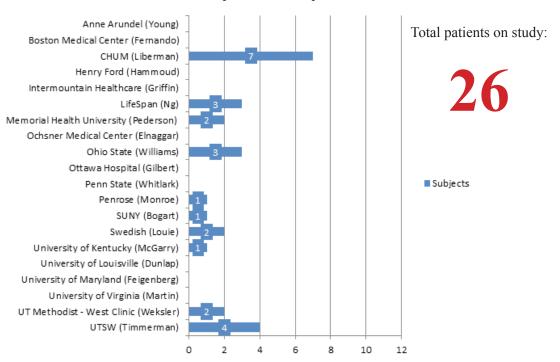
- Mayo Clinic Rochester
- Meridian Health
- Providence Health and Services
- Thomas Jefferson University
- University of Cincinnati
- University of Colorado
- Wake Forest

Completed contracts:

- Karmanos Cancer Center
- Rutgers Cancer Institute of NJ
- UC San Diego

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Jolt-Ca Study Accrual by Site



The Stablemates Clinical Trial

A clinical trial is a research study that is conducted in a medical setting such as a clinic or hospital. It usually involves the testing of a new medication, treatment, or device.

Patients are never placed in a clinical trial without their knowledge and permission. All qualified patients involved in clinical trials consent to participate before treatment begins.

Lung cancer

You have been diagnosed with an early stage lung cancer, meaning the cancerous tumor appears limited to one of the lobes of your lungs. There are three separate lobes on the right and two lobes on the left side of your chest. The standard treatment for early stage lung cancer is lobectomy or removal of an entire tumor-containing lobe. Your doctor can tell you where your lung cancer is positioned and how best to treat low.

What is the Stablemates trial?

The Stablemates trial is comparing two very effective therapies, BOTH of which have a history of being successfully used in the treatment of early stage lung cancer.

- Sublobar resection (removing less than one lobe) is the most common treatment for patients with early stage lung cancer burdened by coexisting serious medical problems. Sublobar resection is a more limited surgery than standard lobectoms, allowing the patient to retain more of their normal lung tissue. Although still a significant surgery requiring a recovery period, sublobar resection is proven to be more tolerable than lobectomy particularly for those with coexisting medical problems.
- Stereotactic ablative radiotherapy (SAbR, also known as SBRT), is a recently developed

radiation therapy technique that is completed in a few painless, outpatient treatments of less than 30 minutes. Recent clinical trials have shown promising results comparable to surgery, and it is now the standard of care given to inoperable patients (those unable to tolerate any form of surgery). But being so new, its performance is still less understood compared to surgical options.

Question: if SABR is so good for those unfit for surgery, could it be used in a broader group including some operable patients? Determining which patients are best suited for either surgery or SABR is one of the primary goals of the Stablemates trial.

How do I participate?

Stablemates is a little different than most other clinical trials. Usually, you agree first to participate and then wait for a blind randomization to determine the particular arm of a study you're assigned.

But we realize that cancer patients prefer to have choices in determining their treatment.

So you get to choose. In Stablemates, patients are prerandomized by a computer and then informed of their assignment before they choose to participate. If you don't like your assignment you are free to decline study participation and choose another therapy in consultation with your doctor.

With this approach, patients can weigh the pros and



Version 4.0 and patient handout

Version 4.0 of the protocol has been IRB-approved and sent to all sites along with a summary of changes.

Among the changes was the addition of a patient information handout. This was created after one of our subsites reported that their patients wanted to have something to take home with them, in addition to the informed consent, to help them think over the decision. This is an example of how the Stablemates team can help remove barriers to participation when sites communicate the issues they encounter.

A pdf of the patient handout is also located on the Stablemates website <u>here</u>. Spanish and French translations will be made available shortly.

Visit the Stablemates website www.joltca.org