El Camino Hospital
THE HOSPITAL OF SILICON VALLEY
TAFT CENTER FOR CLINICAL RESEARCH

Safety and Effectiveness of the Spiration Valve System in Air Leaks (VAST)

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Purpose: To look at safety and efficacy of the investigational device, the Spiration Valve System (SVS) in treating patients with prolonged air leaks in the lungs lasting for more than five days when compared to standard medical management such as chest tube or surgical treatment. Moreover, patients with prolonged air leak are usually poor candidates for surgical intervention and have very few treatment options.

Background: Air leak from the lungs is a post-operative complication that can arise from thoracic surgical operations, including lung volume reduction surgery for patients with emphysema. In fact, advanced emphysema is a risk factor for air leak. Typically air leaks resolve within a week but prolonged air leaks last more than 5 days can significantly increase the length of stay in the hospital, infectious complications and treatment cost.

Mechanism: The (SVS) offers a non-surgical, minimally invasive treatment for patients who have prolonged air leaks. One or more of these valves is placed in the airways that lead to the part of the lungs that are leaking air. The study valves are made to limit the amount of air that can reach the damaged parts of the lungs, but still allows mucus to clear out of these areas. It may provide benefits including better healing and shorter length of stay in a hospital.

Inclusion Criteria

- Age 18 years or older
- Subject has an air leak ≥ 100 mL/min, as measured by a digital thoracic drainage system (DTDS)
- Subject has air leak present on at least the 5th day following origination

Exclusion Criteria

- Subject has air leak only on forced exhalation or cough
- Subject has sepsis
- Subject has pneumonia
- Subject has Acute Respiratory Distress Syndrome (ARDS)
- Subject is not an appropriate candidate for, or unable to tolerate, flexible bronchoscopy procedures
- Subject has a primary pneumothorax
- Subject has undergone a bone marrow transplant
- Subject has undergone a prior intervention (including pleurodesis, surgery, blood patch, and pneumoperitoneum) or valve placement

If you are interested in learning more about this study please visit our website at www.elcaminohospital.org/ClinicalTrials or call Sharmila Vetri Villalan, Clinical Research Coordinator at 650-962-4463.