

Cryospray Therapy Versus Standard of Care for Benign Airway Stenosis (CryoStasis)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Referral to interventional pulmonology or ENT for endoscopic management of suspected benign tracheal stenosis. 2. Significant tracheal stenosis defined by stenosis $\geq 50\%$ of tracheal lumen assessed on chest CT or symptomatology warranting evaluation. 3. Able to provide informed consent 4. Age ≥ 18

Exclusion Criteria:

1. Inability to provide informed consent. 2. Pregnancy 3. Known or suspected malignant central airway stenosis 4. Patient has already been enrolled in this study. 5. Study subject has any disease or condition that interferes with safe completion of the study including: 1. Hypoxemia with need for supplemental oxygen $\geq 2\text{L/min}$ by nasal canula 2. Recent pneumothorax in the previous 12 months 3. Severe COPD (defined as a FEV1/FVC $< 70\%$ and FEV1 $< 30\%$ predicted) and/or severe persistent asthma. 4. Hemodynamic instability with systolic blood pressure < 90 mmHg or heart rate > 120 beats/min, unless deemed to be stable with these values by the attending physicians. 5. Prior complications with SCT 6. Contraindication to rigid bronchoscopy 7. Significant tracheomalacia or alterations in cartilage integrity that would require stent placement or surgical referral as assessed by CT imaging. 8. Greater than 1 BCAS intervention within 6 months before enrollment

Conditions & Interventions

Interventions:

DEVICE: Spray cryotherapy, DEVICE: Ballon Dilation, DEVICE: Radial Incision

Conditions:

Pulmonary Disease

More Information

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Principal Investigator:

Phase: NA

IRB

Number:

System ID: NCT04996173

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