Protocol Introduction

Title:	Prolonged Air Leak (PAL) Blood Patch Intervention Trial
Study Description:	A postoperative autologous blood patch (ABP) intervention trial for patients who underwent lung resection for cancer to examine its effectiveness in preventing a prolonged air leak.
Objective:	To determine the safety and efficacy of autologous blood patch as a means to reduce the rate of prolonged air leak after lung cancer resection.
Study Population:	Patients to undergo elective wedge resection, segmentectomy, lobectomy, or bilobectomy for suspected non-small cell lung cancer (NSCLC) with an air leak on postoperative Day 3.
Number of Participants:	120 Subjects
Subject Participation Duration:	30 Days
Study Duration:	Estimated 24 Months

Study Objectives

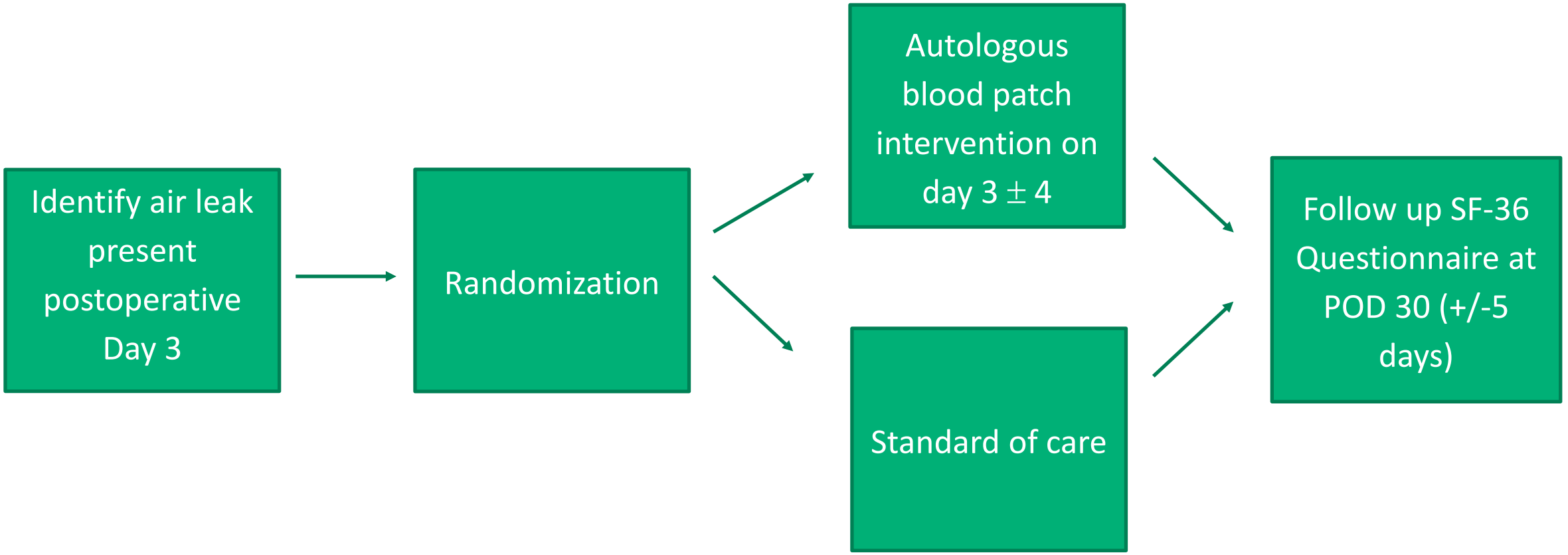
1. **To determine the safety and efficacy of autologous blood patch (ABP) as a means to reduce the rate of prolonged air leak (PAL) after lung cancer resection**

   Hypothesis: The ABP will safely reduce the rate of prolonged air leak in patients with a postoperative air leak

2. **To prospectively examine variation in morbidity and quality of life between patients with and without a PAL**

   Hypothesis: The 30-day morbidity and quality of life will be improved in patients without a prolonged air leak

Study Schema



Data Collected in Electronic Database (REDCap)

- Gender
- Age
- Body Mass Index (BMI)
- Race
- Smoking history and status
- Procedure performed
- Lobe(s) being operated on
- Video Assisted Thoracoscopic Surgery (VATS), Robotic, or Open Operation
- Number of wedge resections in the operation
- Zubrod score (0-5)
- Chronic obstructive pulmonary disease
- Forced expiratory volume in 1 second (FEV1) percent predicted
- Diffusion capacity (DLCO) percent predicted
- Prior cardiothoracic surgery
- Coronary artery disease or congestive heart failure
- Diabetes mellitus
- Chronic renal failure
- Interstitial lung disease
- Preoperative chemotherapy
- Preoperative radiation
- Steroid use
- Clinical and Pathologic TNM stage (AJCC 8th Edition)
- Tumor size per Pathologic Report
- Intraoperative adjunct maneuvers to minimize air leak (buttress, gel, etc)

Outcome Measures:

- Prolonged Air Leak >5 days
- Hospital Length of Stay
- Discharge with Chest tube
- Readmission within 30 days
- In hospital mortality
- 30-day mortality

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