Summary of Primary Spontaneous Pneumothorax Study

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Primary spontaneous pneumothorax (PSP) refers to accumulation of air in the chest cavity between the lung and the chest wall, resulting in collapse of the lung, occurring in a patient without known lung disease or injury. This occurs most commonly in adolescents and young adults, and is often related to cysts on the lung, or blebs, that rupture and leak air. The primary goal of initial treatment for PSP is evacuation of the air from the chest cavity, which allows the lung to re-expand. This can be accomplished by one of two different invasive procedures: simple aspiration or chest tube insertion. Both treatments involve placement of a small tube into the chest to draw out the air, but with simple aspiration the tube is removed immediately after confirmation of lung re-expansion. Chest tube insertion typically involves placement of a slightly larger tube that is left in place for a longer period of time, until confirmation that the air leak has ceased, which requires a prolonged inpatient hospital admission and numerous chest x-rays.

The objective of this multi-center, non-randomized, prospective pilot study is to examine the rate of successful PSP resolution using the simple aspiration technique.

In this study, eligible subjects diagnosed with PSP at eleven participating large children's hospitals will be enrolled and offered a choice of management with either the simple aspiration protocol or management according to their surgeon's preference, which may include simple aspiration, chest tube placement, or rarely, an operation. If the aspiration procedure is deemed a failure at any point, the subject will be managed according to the surgeon's preferences. This choice will be made jointly by the subject and his or her legal guardian. The legal guardian will sign consent, and the child will sign assent for participation in the study. . Potential subjects will be given up to one hour to decide if they wish to participate.

Simple aspiration arm

Subjects in this arm will undergo initial management of their pneumothorax with a simple aspiration procedure. The procedure will involve placement of a small catheter into the chest cavity and applying negative pressure to manually aspirate the air out of the chest cavity, which will allow the lung to re-expand. The aspiration catheter will be less than or equal to 12 French in diameter. Further details of the type of device and size of catheter will be determined by the surgeon and will depend on the devices available for standard practice at each participating institution. The procedure may be performed with local anesthetic, with or without sedation, depending on surgeon judgment and available resources or standard practice at each participating institution. The procedure may be performed with or without image guidance (*i.e.* ultrasound or fluoroscopy) during the aspiration, but a chest X-ray must be obtained at the conclusion of the procedure, with the catheter still in place, to verify successful expansion of the lung and for comparison with subsequent chest X-rays. A small residual pneumothorax after the initial aspiration procedure may still be deemed a success. Successful aspiration at the time of the initial aspiration procedure will be defined as: expansion of the lung apex to the top of the 4th rib or higher and expansion at the lateral chest wall to the 6th rib or higher. A failure will be defined as a residual pneumothorax that is not limited to the apex and extends laterally down the chest wall below the 6th rib. If the first post-procedure chest X-ray demonstrates failure of adequate lung expansion, the existing catheter may be used for one additional aspiration attempt, with application of negative pressure followed by another chest X-ray.

After the aspiration procedure, the subject will be admitted to the hospital for a minimum observation period of 6 hours. The small catheter will be capped and left in place and the insertion site covered by an occlusive dressing, such that this same catheter could be utilized in the event of failure of the aspiration procedure. After 6 hours, a second chest X-ray will be obtained to assess for recurrent pneumothorax or enlargement of a small residual pneumothorax. If the pneumothorax is stable or smaller in size after 6 hours of observation, then the catheter will be removed and the patient discharged to home. However, if the pneumothorax recurs or enlarges after 6 hours, then the aspiration procedure has failed. The existing catheter could be uncapped and used as an indwelling chest tube for a more prolonged period of chest drainage, but all management is according to the surgeon's preference and standard practice. At any time, if the aspiration procedure is determined to be a failure, by either inadequate lung expansion or recurrent pneumothorax, the patient will be managed according to the judgment and standard practice of the treating surgeon.

Preference arm

Subjects that choose the surgeon preference arm of the study are enrolling for prospective data collection only. These subjects will not have any portion their care directed by the study protocol. The decision to proceed with any treatment or intervention will be made jointly by the surgeon and the patient and his or her legal guardian. Any standard treatment option may be utilized, including simple aspiration, chest tube placement, or an operation (VATS). If the surgeon's preference and standard treatment is simple aspiration but the patient does not want the aspiration procedure, then the surgeon will perform an alternative treatment option, such as chest tube placement or VATS.

Entrance Criteria:

Inclusion criteria

1. Age greater than or equal to 12 years and less than 18 years at date of enrollment.
2. First time seeking medical attention for symptoms related to primary spontaneous pneumothorax.
3. Consulting surgeon determines that intervention is required for treatment of spontaneous pneumothorax.

Exclusion criteria

1. Patients with a previous episode of pneumothorax on the same side of the chest that required medical treatment in the past.
2. Pneumothorax is secondary to a co-morbid medical condition (underlying pulmonary disease, malignancy, or trauma).
3. Pneumothorax is small and amenable to observation: size <2cm space between lung and chest wall at the apex and clinically stable patient with minimal symptoms.
4. Bilateral pneumothorax.
5. Unstable patient in need of emergent intervention at surgeon discretion.
6. Patients who are known to be pregnant.
7. Patients in the custody of the state.
8. Patients who are currently prisoners.
9. Non-English speaking.

Spontaneous Pneumothorax Study Algorithm