A Prospective Multi-Center Randomized Post Market Study to Evaluate the PleuraSeal Sealant System as an Adjunct to Standard Closure Techniques for Control of Visceral Pleural Air Leaks Following Elective Pulmonary Resection Via Open Thoracotomy.

Published: 14-03-2008
Last updated: 10-05-2024

This is a prospective, multi-center, randomized, two-arm, single-blind post market study designed to compare standard tissue closure techniques (control) to standard tissue closure techniques plus the PleuraSeal Sealant System (study device) for...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pleural disorders
Study type	Interventional

Summary

ID

NL-OMON31438

Source
ToetsingOnline

Brief title
Protocol LUN-06-002 PleuraSeal * Sealant System

Condition

- Pleural disorders

Synonym
and segmentectomy (limited resection in case of reduced functional operability) in one or

more lobes via an open thoracotomy., The study objective is to further characterize the PleuraSeal Sealant System as compared to standard of care (sutures and staples only) in subjects undergoing an elective pulmonary lobectomy

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Klinisch onderzoek gefinancierd door de Studiesponsor: Confluent Surgical Inc;.

Intervention

Keyword: Pleura Sealant System, post market study, postoperative air leaks, randomized

Outcome measures

Primary outcome

Proportion of subjects remaining air leak free from the time of skin closure to

hospital discharge. (device performance)

Secondary outcome

* Proportion of subjects for whom intra-operative air leak sealing success is

achieved. (device performance)

* Time from skin closure to last observable air leak (device performance)

* Duration of chest drainage (device performance)

* Duration of hospitalization (device performance)

* Incidence of complications (only Cancer progression, Illeus/ Intestinal

Obstruction, Colitis/ gastroenteritis, urinary tract infection, congestive

heart failure, pleural empyema, wound infection and surgical site infections)

(safety)

* Changes form baseline in laboratory values and in laboratory value normal/

abnormal status. (safety)

Study description

Background summary

Currently, Confluent Surgical markets a synthetic, PEG-based hydrogel sealant in the United States and several geographies outside the United States, including the European Union. The PMA approved device, marketed under the trade name *DuraSeal® Dural Sealant System*, is intended for use as an adjunct to standard methods for dural repair, such as sutures, to provide watertight closure. Additionally, DuraSeal is CE Mark approved for the following thoracic indication: to produce a leak-free closure when used during elective pulmonary resection as an adjunct to standard closure techniques of visceral pleural air leaks. Based on the physical properties of the sealant, DuraSeal technology may address shortcomings of other surgical sealants and may provide a safe and effective alternative for producing leak-free closures when used to augment primary visceral pleural repairs. The material is biocompatible and inert. Due to its synthetic nature the material carries no potential for transmitting blood-borne pathogens or for inducing anaphylaxis. Unlike other polymeric sealants, it does not require any primers nor does it require an outside energy source to facilitate the polymerization reaction. Application is simple, with rapid in situ polymerization (within 3 seconds), making it easy to prepare and use. Moreover, the PEG polymer structure and high water composition of the sealant results in a material with low durometer and favorable elastic properties, ideal for lung applications as the material must contract and expand with respiration without limiting normal pulmonary function or pleural surface healing. When used for pulmonary sealing, the DuraSeal material is referred to as the PleuraSeal* Sealant System.

The purpose of this protocol is to further evaluate the safety and performance of Confluent Surgical*s PleuraSeal* Sealant System in the treatment and control of air leaks following elective pulmonary resection via an open thoracotomy. Results from this study, if favorable, will demonstrate that the PleuraSeal surgical sealant provides a convenient, safe and effective surgical tool that can be used as an adjunct to standard closure of visceral pleural air leaks incurred during elective pulmonary resection.

Objective of the study (in English):

Further characterize the PleuraSeal Sealant System as compared to standard of care (sutures and staples) in subjects undergoing an elective pulmonary lobectomy, and segmentectomy (limited resection in case of reduced functional

operability) in one or more lobes via an open thoracotomy.

Study objective

This is a prospective, multi-center, randomized, two-arm, single-blind post market study designed to compare standard tissue closure techniques (control) to standard tissue closure techniques plus the PleuraSeal Sealant System (study device) for control of intraoperative and postoperative air leaks.
Approximately 120 subjects will be randomized in 1:1 ratio either to control group or study device treatment group to obtain 112 subjects required to evaluate the primary endpoint.

Study design

This is a prospective, multi-center, randomized, two-arm, single-blind post market study designed to compare standard tissue closure techniques (control) to standard tissue closure techniques plus the PleuraSeal Sealant System (study device) for control of intraoperative and postoperative air leaks.
Approximately 120 subjects will be randomized in 1:1 ratio either to control group or study device treatment group to obtain 112 subjects required to evaluate the primary endpoint.

Randomization:

Prior to the initiation of the study, a treatment randomization scheme will be generated. Treatment assignments will be placed into a sealed envelope (or other suitable randomization method; e.g., interactive voice response system) thus blinding the surgeon to treatment assignment prior to randomization. Once the closure of the pulmonary resection has been completed to the surgeons* satisfaction and the subject has been confirmed to meet all intra-operative eligibility criteria, subjects will be randomly assigned to either the investigational group or the control group. Group assignments will be performed using a randomization method that will allow for the blinding of the surgeon up to this point. Randomization will be blocked by study center.

Intervention

Following completion of the pulmonary resection procedure, once hemostasis has been achieved, and closure has been completed to the surgeons* satisfaction, a thorough search for air leaks will be performed. Air leak assessment will be accomplished while the lung is partially inflated with instillation of warm sterile saline into the thorax and submersion of the cut or dissected lung surfaces while maintaining mechanical ventilation with an end-inspiratory airway pressure of 20 to 25cm H20.
Subject*s intraoperative eligibility will be confirmed following the first lung submersion leak test. Subjects with no intraoperative leaks will not be

eligible for randomization, but will be followed through hospital discharge in order to quantify if late air leaks occur. For those subjects the CRF Form *Late air leak occurrence* needs to be completed. All other subjects that do not meet intraoperative eligibility criteria will be withdrawn from study participation and not followed. Subjects will then be randomly assigned on a one-to-one (1:1) basis to either the study device or control group

If the subject is randomized to the investigational device: The PleuraSeal Sealant should be applied to all air leaks, areas of dissection, suture and staple lines and raw parenchymal surfaces. The sealant is to be applied with the lung partially inflated so that all target application areas are able to be fully visualized (i.e. no folds in lung tissue) and no active air leaks are present. After all targeted sites have been adequately treated, and following a 10-20 second gel period at the last treated site, the lung submersion leak test should be repeated. Up to two applications of sealant will be allowed in attempt to control air leaks. Each application is defined by the administration of the lung submersion leak test.

If the subject is randomized to control: The PleuraSeal Sealant will not be applied and sutures and staples will be the only standard of care used.

For both study groups (control and investigational device): After the assigned treatment has been completed, a final reassessment and re-grading of air leaks, using the lung submersion leak test will be performed. If no intraoperative air leaks are identified it will be considered a success for the secondary endpoint (i.e. intraoperative sealing success). Inversely, if air leaks are still present it will be considered a failure for the secondary endpoint. Investigators are then able to attempt other techniques designed to control the pleural space, such as pleural tenting or phrenic nerve crush.

Study burden and risks

Taking part in this study may or may not provide any help to the subject. A possible benefit of the PleuraSeal is that it may help reduce the possibility of air leaks and to reduce the problems associated with a leak after lung surgery. This may include reducing the need for prolonged hospital stays and/or re-operations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* * 18 years old
* Scheduled for an elective pulmonary lobectomy, and segmentectomy (limited resection in case of reduced functional operability) in one or more lobes via an open thoracotomy
* Subject has been informed of the nature of the study and has provided written informed consent, approved by the appropriate Ethics Committee (EC) of the respective clinical site
* At least one intraoperative air leak identified during lung immersion leak test after the initial closure is completed
* Hemostasis must be confirmed prior to randomization

Exclusion criteria

* Documented history of bleeding disorders and/or severely altered renal or hepatic function
* Compromised immune system (e.g., HIV/acquired immunodeficiency syndrome, immunosuppressive therapy)
* Prior ipsilateral thoracotomy
* Subject with Tuberculosis
* Extensive adhesions from previous thoracic trauma or surgery
* Undergoing lung volume reduction surgery, wedge resection, pneumonectomy, sleeve

resection or bronchoplasty, blebectomy, bullectomy, pleurodesis, lung transplant , or living lobe transplant donor
* Subject has active systemic or pulmonary infection
* Treated with chronic steroid therapy unless discontinued more than 6 weeks prior to surgery (standard acute perioperative steroids are permitted).
* Pregnant (documented by pregnancy test), breast-feeding, or that wish to become pregnant during the course of the study or not willing to use birth control
* Documented history of uncontrolled diabetes
* Subject has an estimated life expectancy of less than 6 months
* Currently enrolled in another investigational drug or device trial that has not completed the primary endpoint or that clinically interferes with this study
* Congestive heart failure, COR pulmonale or other condition that, in the opinion of the investigator, may jeopardize the subject*s well-being and/or negatively impact the interpretation of data collected during the clinical study
* Unable to comply with the study requirements or follow-up schedule
* Procedure performed via VATS only
* Air leaks originating from bronchioles > 1 mm in diameter that can not be primarily closed or a residual tidal volume loss of * 30%
* Extensive intrathoracic adhesions present
* Exploratory thoracotomy performed only
* Pneumonectomy, wedge resection, sleeve resection, bronchoplasty, blebectomy or bullectomy performed
* Incidental finding of any other pre-operative exclusion criteria
* Use of buttressing materials or other non-autologous staple/suture line reinforcement or other surgical sealants when used for pulmonary sealing (i.e., use of hemostatic agents for hemostasis is permitted)
* Investigator determines that participation in the study may jeopardize the safety or welfare of the subject.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2008
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	PleuraSeal Sealant System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-03-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL20604.029.07