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Utility of BioGlue® surgical adhesive in preventing air leaks in lung volume reduction surgery (LVRS)

Submission date 26/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 24/07/2009	**Overall study status** Completed	
Last Edited 12/07/2016	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2

Study information

Scientific Title
A controlled trial comparing stapling with BioGlue® surgical adhesive versus stapling with buttressed bovine pericardium in lung volume reduction surgery (LVRS)

Study objectives
BioGlue® on staple line is as effective as stapling with pericardial buttressing in reducing air leaks in lung volume reduction surgery (LVRS). Phase 1 will establish the role and efficacy of BioGlue® in LVRS and phase 2 will compare its benefits over buttressed pericardial stapling.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Birmingham East North and Solihull Research Ethics Committee approved in July 2005 (ref: 05 /Q2703/77). Amendment in January 2009.

Study design
Randomised self-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery for emphysema

Interventions
Patients are randomised via sealed randomised envolopes opened on the day of surgery. Patients are then randomised to LVRS with two different adjuncts to staple line:
1. BioGlue®
2. Pericardial buttress

Intervention Type

Other

Phase
Phase IV

Primary outcome measure
To demonstrate an increase in the frequency of an air leak free post-operative hospital course for patients receiving BioGlue® as a pneumostatic sealant as compared to patients receiving the pericardial buttressed stapling. Post-operatively, occurrence of air leaks will be assessed on a per patient basis, twice daily.

Secondary outcome measures
1. Incidence of re-operation due to air leaks
2. Volume of fluid loss in chest tube drain
3. Time to air leak cessation
4. Incidence of complications/adverse events
5. Early (hospital discharge) mortality and late mortality (through final follow-up)

Measured twice daily.

Overall study start date
01/09/2005

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Patients undergoing LVRS
2. Forced expiratory volume in one second (FEV1) less than 40%
3. FEV1/forced vital capacity (FVC) ratio less than 50% following challenges with beta 2 agonists /ipratropium bromide and a trial of oral corticosteroids
4. Residual volume of greater than 140%
5. Severe emphysema with heterogeneity ("target areas") documented on high resolution computed tomography (CT) scans
6. Less than 75 years of age, but greater than 18 years of age, either sex
7. Clinically stable for 1 month before entry to the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Patients who do not consent to the trial
2. Patients with known hypersensitivity to albumin, bovine products, or glutaraldehyde
3. Patients who have been treated with an investigational product and have not completed the entire follow-up period for that investigational product
4. Patients who are unwilling or unable to complete all study evaluations

Date of first enrolment
01/09/2005

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Consultant Thoracic Surgeon
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
Heart of England NHS Foundation Trust (UK)

Sponsor details
Birmingham Heartlands Hospital
Bordesley Green East
Birmingham
England
United Kingdom
B9 5SS

Sponsor type
Hospital/treatment centre

Website
http://www.heartofengland.nhs.uk/

Funder(s)

Funder type
Industry

Funder Name
CryoLife Europa Ltd (UK) - educational grant

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration