

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/07/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 12/07/2016	Condition category Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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 envelopes 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