ISRCTN56543987 https://doi.org/10.1186/ISRCTN56543987

# Prevention by HMGCoA reductase inhibition of Acute Lung Injury (ALI) associated with one lung ventilation following oesophagectomy by a reduction of pulmonary vascular dysfunction and inflammation

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| **Submission date**<br>09/03/2007 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>18/05/2007 | **Overall study status**<br>Completed | |
| **Last Edited**<br>04/04/2014 | **Condition category**<br>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
RGHT000392

# Study information

### Scientific Title

### Acronym
Prevention-HARP

### Study objectives
Treatment with simvastatin can prevent lung injury in humans undergoing oesophagectomy as assessed by important surrogate clinical outcomes.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Office for Research Ethics Committees Northern Ireland (ORECNI). Date of approval: 20/07/2007 (ref: 07/NIR02/83)

### Study design
Prospective, randomised, double-blind, placebo-controlled clinical trial and an in vitro study.

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied
Acute Lung Injury (ALI)

### Interventions
Patients will be randomised to simvastatin 80 mg or placebo enterally for 4 days prior to surgery and up to 7 days following surgery.

### Intervention Type
Other

### Phase

Not Specified

### Primary outcome measure
Efficacy of simvastatin to improve pulmonary deadspace at 6 hours following oesophagectomy or prior to extubation if earlier.

### Secondary outcome measures
1. Oxygenation assessed by the PaO2: FiO2 ratio 6 hours following oesophagectomy
2. Respiratory system compliance (Crs) at 6 hours following oesophagectomy or prior to extubation if earlier
3. Occurrence of Suspected Unexpected Serious Adverse Reactions (SUSARs)

### Overall study start date
01/08/2007

### Completion date
01/08/2010

## Eligibility

### Key inclusion criteria
Adult patients undergoing oesophagectomy.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
40

### Key exclusion criteria
1. Age < 18 years
2. Pregnancy
3. Creatine Kinase (CK) > 5 times upper limit of normal range
4. Transaminases > 3 times upper limit of normal range
5. Severe renal impairment (calculated creatinine clearance less than 30 mL/minute)
6. Severe liver disease (Childs Pugh score > 11)
7. Participation in other trials within 30 days
8. Current treatment with statins
9. Inability to take oral medication pre-operatively
10. Patients taking corticosteroids or non-steroidal anti-inflammatory drugs
11. Consent declined

### Date of first enrolment
01/08/2007

**Date of final enrolment**
01/08/2010

# Locations

**Countries of recruitment**
Northern Ireland

United Kingdom

**Study participating centre**
**Intensive Care Unit**
Belfast
United Kingdom
BT12 6BA

# Sponsor information

**Organisation**
The Royal Group of Hospitals Trust (UK)

**Sponsor details**
Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT126BA

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.royalhospitals.org/contacts/index.php

**ROR**
https://ror.org/02tdmfk69

# Funder(s)

**Funder type**
Not defined

**Funder Name**
Doctoral fellowship scheme, Central Services Agency (UK)

**Funder Name**
REVIVE  Charity for the regional intensive care unit, the Royal Group of Hospitals Trust (UK)

# 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/01/2014 | | Yes | No |