# 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

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

**Plain English summary of protocol**Not provided at time of registration

#### Contact information

Type(s)

Scientific

Contact name

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Contact details

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### Additional identifiers

Protocol serial number 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

#### Study type(s)

**Not Specified** 

#### 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(s)

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

#### Key secondary outcome(s))

- 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)

#### Completion date

# **Eligibility**

#### Key inclusion criteria

Adult patients undergoing oesophagectomy.

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Αll

#### 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

United Kingdom

Northern Ireland

# Study participating centre Intensive Care Unit

Belfast

# Sponsor information

#### Organisation

The Royal Group of Hospitals Trust (UK)

#### **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**

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