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