

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	☒ Prospectively registered ☐ Protocol
Registration date 18/05/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 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

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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)

Primary study design

Interventional

Study design

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

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

01/08/2010

Eligibility

Key inclusion criteria

Adult patients undergoing oesophagectomy.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom
BT12 6BA

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