ISRCTN61546997 https://doi.org/10.1186/ISRCTN61546997

A randomised trial of a Lung-Open Ventilation Strategy in acute lung injury

Submission date
11/08/2005

Recruitment status
No longer recruiting

Registration date
11/08/2005

Overall study status
Completed

Last Edited
18/02/2008

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00182195

Protocol serial number
MCT-38141

Study information

Scientific Title

Acronym
LOVS

Study objectives
The Lung Open Ventilation strategy may reduce mortality, other organ dysfunction, and the duration of mechanical ventilation, intensive care, and hospital stay.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Hamilton Health Sciences/McMaster University Research Ethics Board, 15/06/2004

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Critically Ill Patients with Acute Lung Injury (ALI)

Interventions
Control Ventilation Strategy (assist control; low tidal volume; low airway pressures; standard PEEP)
Experimental Lung Open Ventilation Strategy (pressure control; low tidal volumes; low airway pressures; high PEEP; recruitment maneuvers).

For further information, please contact Dr Meade at the address listed below or Dr Thomas Stewart at University of Toronto (tstewart@mtsinai.on.ca).

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Hospital Mortality

Key secondary outcome(s))

1. Mortality attributed to respiratory failure
2. Duration of respiratory failure and duration of mechanical failure
3. Evaluation of respiratory function during mechanical ventilation
4. Incidence of barotrauma
5. Non-respiratory organ dysfunction

Completion date
31/01/2006

Eligibility

Key inclusion criteria
Persons of either sex 18 years and older.
1. Invasive mechanical ventilation
2. Acute respiratory insufficiency (within past 28 days)
3. Bilateral infiltrates on frontal chest radiograph
4. Hypoxemia, defined as paO2/FiO2 less than or equal to 250, on any amount of Positive End-Expiratory Pressure (PEEP)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Primary cause of respiratory failure is cardiac
2. Anticipated duration of mechanical ventilation <48 hours, as judged by the intensivist
3. Inability to wean from other experimental ventilation strategies
4. Severe chronic respiratory disease
5. Neuromuscular disease that will result in prolonged need for mechanical ventilation
6. Conditions where hypercapnia-induced intracranial hypertension should be avoided
7. Morbid obesity (>1 kg per cm body weight)
8. Pregnancy
9. Very unlikely to survive in the judgment of the investigator, and luck of commitment to life support
10. Malignancy or underlying irreversible condition with 6 month mortality greater than or equal to 50%

11. Greater than 48 hours elapsed since first eligible in study hospital
12. Current participation in competing trial
13. Lack of physician, patient or proxy consent

Date of first enrolment
01/08/2000

Date of final enrolment
31/01/2006

Locations

Countries of recruitment
Canada

Study participating centre
Clinical Epidemiology & Biostatistics
Hamilton, Ontario
Canada
L8N 3Z5

Sponsor information

Organisation
McMaster University (Canada)

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-38141)

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	13/02/2008		Yes	No