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

Submission date	Recruitment status	[ ] Prospectively registered
11/08/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/08/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/02/2008	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00182195

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Hospital Mortality

Secondary outcome measures
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

Overall study start date
01/08/2000

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
980

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
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L8N 3Z5

Sponsor information

Organisation
McMaster University (Canada)

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Sponsor type

University/education

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

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	13/02/2008		Yes	No