

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

Submission date 11/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/08/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/02/2008	Condition category Respiratory	<input type="checkbox"/> 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

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@mtsina.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 $\text{paO}_2/\text{FiO}_2$ 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 lack 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)

Sponsor details

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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