

Influence of support on intra-abdominal pressure, hepatic kinetics of indocyanine green and extravascular lung water during Prone Positioning (PP) in ARDS patients: a randomised crossover study

Submission date 26/04/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/04/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/07/2007	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

Protocol serial number
N/A

Study information

Scientific Title

Study objectives

The aim of the present study was to investigate whether the evolution of Intra-Abdominal Pressure (IAP), liver function assessed by the Plasma Disappearance Rate of Indocyanine Green (PDRICG) and extravascular lung water is related to the type of support during PP. We therefore prospectively compared, in a population of medical-Acute Respiratory Distress Syndrome (ARDS) patients, the effects of an air-cushioned mattress and a conventional foam mattress during PP.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Acute Respiratory Distress Syndrome (ARDS)

Interventions

Baseline measurements were performed in the supine position after one hour of steady-state conventional mechanical ventilation. Then the following two periods of PP were randomised:

1. 6 hours of PP on the moulded foam mattress
2. 6 hours of PP on the air-cushioned mattress

A period of 18 hours in the supine position separated the two periods in the prone position. Each patient was his or her own control. Measurements were achieved in the supine position, after 1 and 6 hours of PP.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Intra-Abdominal Pressure (IAP)
2. Plasma Disappearance Rate of Indocyanine Green (PDRICG)
3. Extravascular Lung Water (EVLW)
4. Partial Pressure of Oxygen in Arterial Blood (PaO₂)/Fraction of Inspired Oxygen (FiO₂) ratio

5. Central Venous Pressure (CVP)
6. Mean pulmonary arterial pressure
7. Pulmonary artery occlusion pressure

Key secondary outcome(s))

No secondary outcome measures

Completion date

01/01/2004

Eligibility

Key inclusion criteria

Twenty consecutive patients with ARDS were included and turned prone in the medical intensive care unit of Sainte Marguerite University Hospital in Marseille, France. Patients were prospectively included in this study after obtaining written informed consent from the next of kin. The study design was approved by the Comité Consultatif de Protection des Personnes dans la Recherche Biomédicale of Marseille. ARDS was defined in accordance with the recommendations of the American/European Consensus Conference.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Patients with unstable cardiovascular function, cerebral injury or unstable spinal fractures, patients subjected to major abdominal surgery and patients with a history of neuromuscular disease were excluded.

Date of first enrolment

01/01/2003

Date of final enrolment

01/01/2004

Locations

Countries of recruitment

France

Study participating centre
Département d'Anesthésie Réanimation
Marseille
France
13009

Sponsor information

Organisation
Sainte Marguerite Hospital (France)

ROR
<https://ror.org/0338wkj94>

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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	01/06/2005		Yes	No