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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

Registration date
26/04/2005

Overall study status
Completed

Last Edited
27/07/2007

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

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 measure
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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2003

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
20

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
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13009

Sponsor information

Organisation
Sainte Marguerite Hospital (France)

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-
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0338wkj94

Funder(s)

Funder type

Not defined

Funder Name
Not provided at time of registration

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	01/06/2005		Yes	No