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Comparison of the effects of spontaneous breathing trial with T-piece versus pressure-support ventilation in patients recovering from cardiac surgery: a randomised controlled pilot study

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
10/11/2011

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
N0205182184

Study information

Scientific Title

Study objectives
To compare the mean levels of anxiety reported by two groups of patients using a Visual Analogue Scale (VAS) at specific time points during spontaneous breathing trials with:
1. The T-piece method, or
2. Pressure-support ventilation (PSV) of 10 cm H2O with positive end expiratory pressure (PEEP) 5 cm H2O

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Spontaneous breathing after ventilation

Interventions
Patients are randomised to:
1. The T-piece method
2. Pressure-support ventilation (PSV) of 10 cm H2O with positive end expiratory pressure (PEEP) 5 cm H2O

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome(s)
Anxiety scores before operation, at PSV of 10 cm H2O with PEEP of 5 cm H2O, 30-minute after PSV of 10 cm H2O with PEEP of 5 cm H2O, before extubation, one hour after extubation and before discharge from ICU.

Key secondary outcome(s)
No secondary outcome measures

Completion date
30/09/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
22/03/2006

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
ITU
London
United Kingdom
E2 9JX

Sponsor information

Organisation

Funder(s)

Funder type
Government

Funder Name
Barts and The London NHS Trust (UK)

Funder Name
NHS R & D Support Funding (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration