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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
No secondary outcome measures

Overall study start date
22/03/2006

Completion date
30/09/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
45

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
England

United Kingdom

Study participating centre
ITU
London
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

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

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