

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/11/2011	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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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