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Comparison of anaesthetic face masks - a crossover trial to compare air entrainment using the standard BOC mask vs the intersurgical single use mask during preoxygenation

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 21/07/2008	**Condition category** Surgery	

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
N0391148230

Study information

Scientific Title

Study objectives
Null hypothesis: that there will be no difference in the expired oxygen concentration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Cross over randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Anaesthesia

Interventions
20 to 30 subjects randomised into 2 groups. Each group will undergo 2 cycles of 3 minutes preoxygenation with each of the test masks, attached to the same anaesthetic circuit.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure

1. Comparison of area under the curve for expired oxygen concentration against time over 3 minutes.
2. Comparison of inspired oxygen concentrations against time over the 3 minutes.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2004

Completion date
31/03/2005

Eligibility

Key inclusion criteria
Between 20-30 subjects recruited from non-anaesthetic colleagues.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
30 healthy volunteers recruited from colleagues

Key exclusion criteria
Respiratory disease, significant cardiac disease.

Date of first enrolment
01/09/2004

Date of final enrolment
31/03/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

West Dorset General Hospitals NHS Trust
Dorchester
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
West Dorset General Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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	01/04/2007		Yes	No