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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Andy Ball

Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Not Specified

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(s)

- 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.

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/03/2005

Eligibility

Key inclusion criteria

Between 20-30 subjects recruited from non-anaesthetic colleagues.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

United Kingdom

England

Study participating centre West Dorset General Hospitals NHS Trust

Dorchester United Kingdom DT1 2JY

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

West Dorset General Hospitals NHS Trust (UK)

Funder Name

NHS R&D Support Funding

Results and Publications

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