

# 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

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/07/2008	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**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  
United Kingdom  
DT1 2JY

## **Sponsor information**

### **Organisation**

Department of Health

### **Sponsor details**

Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

### **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?
<a href="#">Results article</a>	results	01/04/2007		Yes	No