

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

**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

### Primary study design

Interventional

### Study design

Cross over randomised controlled trial

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