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A comparison of pre-oxygenation with patients in the reclined versus supine position

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 17/12/2008	**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
N0065101825

Study information

Scientific Title

Study objectives
Does positioning a patient in a reclined versus a supine position before pre-oxygenation improve the efficacy of this process? Primary null hypothesis is that positioning a patient 20 head-up will not effect the efficacy of pre-oxygenation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
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: Cholecystomy

Interventions
20 women will be randomised to receive oxygen in the usual way.
20 women will receive oxygen in a slightly reclined position.

Monitors will be used to determine which group of patients demonstrates the most oxygen stored in their body. Patients will be connected to a breathing machine via a tube placed in their throat after they are asleep. The study also aims to investigate which position (lying flat or slightly reclined) provides the best view of the patient's throat when placing the tube.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2001

Completion date
01/09/2003

Eligibility

Key inclusion criteria
40 female patients undergoing cholecystomy.

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
40

Key exclusion criteria
Pregnant patients will be excluded.

Date of first enrolment
01/11/2001

Date of final enrolment
01/09/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anaesthesia
Sunderland

United Kingdom
SR4 7TP

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
City Hospitals Sunderland NHS Trust (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2005		Yes	No