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A randomised controlled trial of post-operative high dependency care

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 05/04/2012	**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
N0224135100

Study information

Scientific Title

Study objectives
To determine whether post-operative high dependency care can decrease morbidity and mortality in patients who would otherwise be cared for on a general surgical ward.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery: Post operative care

Interventions
Patients are randomised to high dependency care or general surgical ward care.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
1. The incidence of postoperative mortality and major morbidity (cardiorespiratory) in high dependency unit (HDU) compared to general surgical ward.
2. The duration of postoperative care (on HDU and in the hospital)

Secondary outcome measures

Not provided at time of registration

Overall study start date
31/07/2002

Completion date
30/03/2007

Eligibility

Key inclusion criteria
Adult patients scheduled for colorectal surgery. Patients with a low exercise tolerance (AT <11 ml Oxygen/kg/min) recruited into trial.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
31/07/2002

Date of final enrolment
30/03/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
South Devon Health Care NHS Trust
Torquay
United Kingdom
TQ2 7AA

Sponsor information

Organisation
Department of Health

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

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
South Devon Healthcare 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	01/02/2012		Yes	No