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Validity of the six minute walk test as a surrogate for the anaerobic threshold in the pre-operative assessment clinic

Submission date 10/10/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/11/2008	**Overall study status** Completed	
Last Edited 28/03/2013	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Gerard Danjoux

Contact details
Department of Anaesthesia
Cheriton House
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1 July 2008

Study information

Scientific Title

Study objectives
The aim of this study is to examine the validity of the six minute walk test (6MWT) (maximum distance walked; undertaken at pre-operative assessment for scheduled major non-cardiac surgery) against two criterion measures derived from cardiopulmonary exercise testing (CPET) - anaerobic threshold (AT) and peak oxygen consumption (VO2 peak).

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Humber Research Ethics Committee gave approval on the 27th August 2008 (ref: 08 /H1305/62).

Study design
Prosepective observational concurrent validity study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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
Pre-operative assessment

Interventions
This is a concurrent validity study. In practice all participants will complete two exercise tests during their attendance at the pre-operative assessment clinic. After gaining consent the participants will first perform a cardiopulmonary exercise test using a cycle ergometer. Then after a rest period they will complete a supervised six minute walk test. The results of the two tests will be read after completion. Patient characteristics and risk assessment data will be collected from the notes during the clinic. The participant will have no further involvement after this clinic attendance. We will collect post-hoc surgical outcome data after discharge from hospital.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
The outcome of a concurrent validity study is determined by the two criterion measures (AT and VO2 peak) and the two predictors (walking distance and body weight product). This will allow us to calculate the typical predictive error in the estimation of AT from the results of a 6MWT. This is measured during clinic attendance.

Secondary outcome measures
Recorded after discharge from hospital:
1. Morbidity and mortality, 30-day mortality also collected 30 days from discharge
2. Length of stay in critical care, measured in days
3. Length of stay in hospital, measured in days
4. Further measures of pre-operative assessment will be analysed in order to best assess the estimation of exercise capacity

Overall study start date
01/10/2008

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Aged between 50 and 85 years of age, either sex
2. Awaiting major surgery for: colorectal resection, upper gastrointestinal tract disease, major vascular procedures, major urological and major gynaecological procedures
3. Identified through the surgical pre-operative assessment clinics where participants are routinely assessed prior to surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Emergency surgery
2. Aged less than 50 and greater than 85 years

3. Medical conditions causing inability to walk
4. Unable to complete baseline CPET test
5. Unable to give informed consent
6. Medical contraindications to CPET and 6MWT:
6.1. New York Heart Association Functional Classification greater than or equal to Class III
6.2. Canadian Cardiovascular Society Angina Grading Scale greater than or equal to Class III
6.3. European Society of Hypertension Classification Grades greater than or equal to III
7. Aortic stenosis greater than or equal to moderate (i.e. valve area less than 1.0 cm^2)
8. Hypertrophic cardiomyopathy
9. Symptomatic arrhythmias
10. Spinal cord injury
11. Primary muscular disorder
12. Uncontrolled epileptic seizures
13. Pregnancy

Date of first enrolment
01/10/2008

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anaesthesia
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
James Cook University Hospital (UK)

Sponsor details
Marton Road
Cleveland
Middlesbrough
England
United Kingdom
TS4 3BW

Sponsor type
Hospital/treatment centre

Website
http://www.southtees.nhs.uk/live/

ROR
https://ror.org/02vqh3346

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
James Cook University Hospital (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	01/01/2012		Yes	No