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A study into the effect of mechanical bowel preparation on aerobic exercise capacity as measured by cardiopulmonary exercise testing

Submission date 22/11/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/01/2011	**Overall study status** Completed	
Last Edited 06/02/2014	**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
v6.3

Study information

Scientific Title
Randomised controlled crossover trial of Picolax® and pre-operative cardio-pulmonary exercise testing

Acronym
PicoPEX

Study objectives
1. Does mechanical bowel preparation and fasting influence aerobic exercise capacity as characterised by performance in a cardiopulmonary exercise test?
2. Does a carbohydrate-loading drink influence aerobic exercise capacity as characterised by performance in a cardiopulmonary exercise test?

We hypothesise that mechanical bowel preparation may have a profound impact on aerobic exercise capacity as measured by CPET in patients undergoing elective colorectal surgery. Any impact would be limited by avoidance of bowel preparation and administering oral carbohydrate. We will initially test this hypothesis on healthy volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The South West Research Ethics Committee (REC) approved on the 22nd February 2010 (ref: 09 /H0206/63)

Study design
Pilot prospective single centre blinded randomised controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Colorectal surgery

Interventions

Cardiopulmonary Exercise Test (CPET)
CPET will be performed by all participants in the afternoon of the day of testing. The test will be done in accordance with the consensus protocol from UK centre with reference to ATS / ACCP recommendations. Anaerobic threshold will be determined by the V slope method and correlation with ventilatory equivalents.

All participants will be encouraged to exercise until their maximum effort has been achieved irrespective of the intervention group. Bias may be introduced with less-than-maximal performance, which would be reflected by a reduced Peak V02. The Anaerobic Threshold is effort-independent and hence participant effort will not affect its value.

Participants will be randomised to receive either
1. Picolax®
On the day prior to CPET, participants will have clear fluids only and take one sachet of Picolax® at 8am and 4pm. Each individual will receive two litres of Hartmanns Solution (Macopharma, Twickenham, UK) infused over six hours in the morning prior to CPET. This will reflect usual practice for individuals taking MBP in our Trust.

2. Carbohydrate-Loading Drinks
Each individual will drink two cartons of Ensure/Enlive® nutritional supplements the night before and then 400 mls of carbohydrate-loading drinks (Pre-Op, Nutricia, UK) two hours prior to CPET as per ERAS protocol. They can have breakfast (by 8am) on the day of testing and then only clear fluids until the carbohydrate-loading drinks.

Frequency of testing is three times per participant with at least one week duration between the different interventions.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Picolax®

Primary outcome measure
Exercise capacity, assessed by CPET

Secondary outcome measures
No secondary outcome measures

Overall study start date
21/11/2010

Completion date
31/01/2011

Eligibility

Key inclusion criteria

1. Healthy American Society of Anesthesiologists (ASA) 1 Males
2. Willingness to participate

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
9

Key exclusion criteria
1. ASA II or more

Absolute (definitive and independent) criteria:
2. Acute myocardial infarction (35 days)
3. Unstable angina
4. Uncontrolled arrhythmias causing symptoms or haemodynamic compromise
5. Syncope
6. Active endocarditis
7. Acute myocarditis or pericarditis
8. Symptomatic severe aortic stenosis
9. Uncontrolled heart failure
10. Acute pulmonary embolus or pulmonary infarction
11. Thrombosis of lower extremities
12. Suspected dissecting aneurysm
13. Uncontrolled asthma
14. Pulmonary oedema
15. Room air desaturation at rest < 85%*
16. Respiratory failure
17. Acute non-cardiopulmonary disorder that may affect exercise performance or be aggravated by exercise (i.e. infection, renal failure, thyrotoxicosis)
18. Previous reaction to mechanical bowel preparation

Relative (dependent or related to other factors) criteria:
19. Left main coronary stenosis or its equivalent
20. Moderate stenotic valvular heart disease
21. Severe untreated arterial hypertension (200 mm Hg systolic, 120 mm Hg diastolic)
22. Tachyarrhythmias or bradyarrhythmias
23. High-degree atrioventricular block
24. Hypertrophic cardiomyopathy
25. Significant pulmonary hypertension
26. Advanced or complicated pregnancy
27. Electrolyte abnormalities
28. Orthopaedic impairment that compromises exercise performance

Date of first enrolment

21/11/2010

Date of final enrolment
31/01/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anaesthesia
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Sponsor information

Organisation
Plymouth Hospitals NHS Trust (UK)

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Sponsor type
Not defined

ROR
https://ror.org/05x3jck08

Funder(s)

Funder type

Charity

Funder Name
Gastrointestinal Research Study Fund (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?
HRA research summary			28/06/2023	No	No