

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
Registration date 10/01/2011	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 06/02/2014	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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)

Primary study design

Interventional

Study design

Pilot prospective single centre blinded randomised controlled crossover trial

Study type(s)

Treatment

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(s)

Exercise capacity, assessed by CPET

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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

United Kingdom

England

Study participating centre

Department of Anaesthesia
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation

Plymouth Hospitals NHS Trust (UK)

ROR

<https://ror.org/05x3jck08>

Funder(s)

Funder type

Charity

Funder Name

Gastrointestinal Research Study Fund (UK)

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?
HRA research summary			28/06/2023	No	No