

Randomised controlled, double blinded single centre trial to assess the effects of peri-operative dopexamine on morbidity after major abdominal surgery in patients with low anaerobic threshold

Submission date 01/08/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 18/08/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/10/2012	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
DOP06

Study information

Scientific Title

Study objectives

That using a combination of fluid and dopexamine will reduce the post operative morbidity of patients undergoing elective major abdominal surgery who have a low anaerobic threshold.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by York Research Ethics Committee.

Study design

Randomised, controlled, double blinded trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Major Abdominal Surgery

Interventions

As of 12/03/2008 the anticipated end date of this trial was extended to 1st February 2009. The previous anticipated end date was 1st February 2008.

Infusion of dopexamine at 0.5 mcg/kg/min for 24 hours. The control group receives placebo (normal saline) as an infusion for 24 hours.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Dopexamine

Primary outcome(s)

Morbidity at five, ten, and 15 days using the Post-Operative Morbidity Score (POMS) score.

Key secondary outcome(s)

1. Length of stay in hospital after surgery
2. Recovery parameters (drinking, eating, mobilising)
3. Incidence of post-operative complications

4. Peri-operative haemodynamic variables (heart rate, blood pressure, Central Venous Pressure [CVP])
5. Physiologic and Operative Severity Score for the enUmeration of Mortality and morbidity (POSSUM) score for surgical risk assessment
6. Oxygen delivery

Completion date

01/02/2009

Eligibility

Key inclusion criteria

Patients undergoing scheduled resection for carcinoma of the colon, rectum, bladder, pancreas, stomach or kidney, who, after routine Cardiopulmonary exercise (CPX) testing at the Pre-assessment Clinic, have been found to have an Anaerobic Threshold (AT) less than or equal to 11.0 ml/min/m² as measured by the V-slope method 15, or with an AT of 11.0 -14.0 ml/min/m² and ischaemic changes on Electrocardiogram (ECG) monitoring during testing or with a significant history of ischaemic heart disease (New York Heart Association [NYHA] classification III and IV).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Less than 60 years of age unless they have significant co-morbidities (American Society of Anaesthesiologists (ASA) score three or greater)
2. Having emergency or vascular procedures
3. ASA grade five
4. Refuse or are unable to give informed consent
5. Hypertrophic Obstructive Cardiomyopathy, aortic stenosis, phaeochromocytoma, a low platelet count, or have used a monoamine oxidase inhibitor within the last 14 days

Date of first enrolment

01/09/2006

Date of final enrolment

01/02/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

York Hospital

York

United Kingdom

YO31 8HE

Sponsor information

Organisation

York Hospitals NHS Trust (UK)

ROR

<https://ror.org/027e4g787>

Funder(s)

Funder type

Research organisation

Funder Name

Association of Anaesthetists (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?
Results article	results	01/01/2011		Yes	No