ISRCTN33549216 https://doi.org/10.1186/ISRCTN33549216

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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/08/2006	**Overall study status** Completed	
Last Edited 19/10/2012	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Simon Davies

Contact details
York Hospital
Wigginton Road
York
United Kingdom
YO31 8HE
+44 (0) 190 463 1313
simon.davies@york.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/09/2006

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

Age group
Adult

Sex
Both

Target number of participants
124

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
England

United Kingdom

Study participating centre
York Hospital
York
United Kingdom
YO31 8HE

Sponsor information

Organisation
York Hospitals NHS Trust (UK)

Sponsor details
York Hospital
Wigginton Road
York
England
United Kingdom
YO31 8HE
+44 (0) 190 463 1313
caroline.mozley@york.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.yorkhealthservices.org/

ROR
https://ror.org/027e4g787

Funder(s)

Funder type
Research organisation

Funder Name
Association of Anaesthetists (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	01/01/2011		Yes	No