

# 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

<b>Submission date</b> 01/08/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/08/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/10/2012	<b>Condition category</b> Surgery	<input type="checkbox"/> 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

**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/m<sup>2</sup> as measured by the V-slope method 15, or with an AT of 11.0 -14.0 ml/min/m<sup>2</sup> 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

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**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?
<a href="#">Results article</a>	results	01/01/2011		Yes	No