

# Microvascular Imaging During Abdominal Surgery (MIDAS)

<b>Submission date</b> 25/07/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/07/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/09/2015	<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**  
10093

# Study information

## Scientific Title

Does intra-operative goal directed fluid therapy (GDT) alter microvascular circulation and reduce clinically important post-operative complications in patients undergoing elective major abdominal surgery?

## Acronym

MIDAS

## Study objectives

RCT of algorithm driven intraoperative goal directed vs standard fluid therapy during major rectal and urological surgery. Uncalibrated pulse power analysis (LiDCO rapid) used to quantify nominal cardiac stroke volume. Prior to surgery patients separated into aerobically fit and unfit strata by performance on cardiopulmonary exercise test. clinical outcome is Day 5 POMS (complications ) score. Perioperative microcirculatory changes also

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

ref: 10/H0203/68

## Study design

Randomised interventional single-centre 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 the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Anaesthetics

## Interventions

Goal directed fluid therapy, supplementary gelatin colloid boluses delivered by investigator according to algorithm based on stroke volume variability and stroke volume as shown by LiDCO rapid;

Follow Up Length: 3 month(s)

**Intervention Type**

Procedure/Surgery

**Phase**

Not Applicable

**Primary outcome measure**

Profile of Mood States (POMS) score measured at Day 5

**Secondary outcome measures**

Microvascular indices measured at baseline, post induction, end operative and on day 1 post operative

**Overall study start date**

03/03/2011

**Completion date**

03/03/2013

**Eligibility****Key inclusion criteria**

1. Patients having Rectal Resections or cystectomy
2. Male & female participants
3. Lower age limit = 18 years

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

UK Sample Size: 220; Description: web based minimisation used to stratify participants according to aerobic fitness and operation type (open or lap assisted rectal ) & major urology

**Key exclusion criteria**

Absolute: Unwillingness to participate Inability to perform the tests and consent within the timetable for elective surgery Withdrawn by anaesthetist or surgeon Requirement by the attending anaesthetist to use cardiac output monitoring based on clinical need Acute myocardial infarction (3-5 days) Unstable angina Uncontrolled arrhythmias causing symptoms or haemodynamic compromise Syncope Active endocarditis Acute myocarditis or pericarditis Symptomatic severe aortic stenosis Uncontrolled heart failure Acute pulmonary embolus or pulmonary infarction Thrombosis of lower extremities Suspected dissecting aneurysm

Uncontrolled asthma Pulmonary edema Room air desaturation at rest < 85%\* Respiratory failure  
Acute noncardiopulmonary disorder that may affect exercise performance or be aggravated by  
exercise (i.e. infection, renal failure, thyrotoxicosis)

Relative: Left main coronary stenosis or its equivalent Moderate stenotic valvular heart disease  
Severe untreated arterial hypertension at rest (200 mm Hg systolic, 120 mm Hg diastolic)  
Tachyarrhythmias or bradyarrhythmias Highdegree atrioventricular block Hypertrophic  
cardiomyopathy Significant pulmonary hypertension Advanced or complicated pregnancy  
Electrolyte abnormalities Orthopaedic impairment that compromises exercise performance

**Date of first enrolment**

03/03/2011

**Date of final enrolment**

03/03/2013

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Derriford Hospital**

Plymouth

United Kingdom

PL6 8DH

## **Sponsor information**

**Organisation**

Plymouth Hospitals NHS Trust (UK)

**Sponsor details**

Derriford Hospital

Derriford Road

Crownhill

Plymouth

England

United Kingdom

PL6 8DH

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.plymouthhospitals.nhs.uk/>

**ROR**

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

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

National Institute of Academic Anaesthesia (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**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	results	01/10/2015		Yes	No