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Microvascular Imaging During Abdominal Surgery (MIDAS)

Submission date	Recruitment status	[ ] Prospectively registered
25/07/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/07/2012	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/09/2015	Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Gary Minto

Contact details
Department of Anaesthesia
Derriford Hospital
Derriford Road
Crownhill
Plymouth
United Kingdom
PL6 8DH

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 nomincal 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 variablity 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

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2015		Yes	No