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The effect of 'goal directed' fluid management during gynaecological oncology surgery using the oesophageal Doppler probe

Submission date 23/05/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/08/2010	**Overall study status** Completed	
Last Edited 04/10/2017	**Condition category** Surgery	

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

N/A

Study information

Scientific Title
The effect of intra-operative fluid optimisation using the oesophageal Doppler monitor in gynaecological oncology surgery

Study objectives
Goal directed optimisation of intra-operative haemodynamics using oesophageal Doppler monitoring reduces length of hospital stay and improves outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre interventional prospective double-blinded randomised controlled 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
Gynaecological oncology surgery

Interventions
Two groups: control and protocol group.

Both groups will have DP6 Doppler probe (product code 9070-7001) inserted at the time of intubation. All patients will have standard pre-operative, intra-operative and post-operative care. Fluids (crystalloid, colloid and blood/blood products) will be given at the discretion of the anaesthetist, guided by standard haemodynamic monitoring and operative losses.

Only the protocol group will have direct measurement of central vascular flow using CardioQ-ODM monitor (product code 9051-7056) including corrected flow time (FTc), stroke volume (SV),

stroke distance (SD) and peak velocity (PV) and small colloid (fluid) challenges to maintain FTc greater than 0.35 seconds and optimise SV.

The intervention will last until the end of the operation and the probe will be removed at the time of extubation.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
The aim of this study is to compare the effect of a target driven intra-operative intravenous fluid management using oesophageal Doppler to a standard fluid regimen on complication rate after surgery for corpus uteri, ovarian and cervical cancer. Measured until 5th post-operative day.

Secondary outcome measures
To evaluate the effect of target driven intra-operative fluid management using oesophageal Doppler on hospital stay, measured on day of discharge.

Overall study start date
01/11/2010

Completion date
01/05/2012

Eligibility

Key inclusion criteria
1. Patients aged 20 - 85 years, female
2. Recruited from the Queen Elizabeth Hospital, Gateshead
3. Written informed consent
4. Undergoing elective major gynaecological oncology surgery for ovarian, endometrial and cervical carcinoma

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
70 patients in each group (140 in total)

Key exclusion criteria

Contraindication to oesophageal Doppler use:
1. Oesophageal surgery or stent
2. Oesophageal stricture
3. Oesophageal varices
4. Pharyngeal pouch
5. Moderate/severe aortic valve disease
6. Patient refusal

Date of first enrolment
01/11/2010

Date of final enrolment
01/05/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Elizabeth Hospital
Gateshead
United Kingdom
NE9 6SX

Sponsor information

Organisation
Gateshead Health NHS Foundation Trust (UK)

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c/o Mrs Alison Harvey
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Sponsor type

Hospital/treatment centre

Website
http://www.gatesheadhealth.nhs.uk/index.php

ROR
https://ror.org/01aye5y64

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Northern Gynaecological Oncology Centre (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