

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

<b>Submission date</b> 23/05/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 04/08/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 04/10/2017	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

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

### **Study type(s)**

Treatment

### **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(s)**

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.

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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**

United Kingdom

England

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

## **Sponsor information**

**Organisation**  
Gateshead Health NHS Foundation Trust (UK)

**ROR**  
<https://ror.org/01aye5y64>

## **Funder(s)**

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Northern Gynaecological Oncology Centre (UK)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration