

# 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

Miss Khadra Galaal

### Contact details

Northern Gynaecological Oncology Centre  
Queen Elizabeth Hospital  
Sheriff Hill  
Gateshead  
United Kingdom  
NE9 6SX  
+44 (0)191 445 2597  
khadra.galaal@ghnt.nhs.uk

## 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)

**Sponsor details**

c/o Mrs Alison Harvey

Research and Development

Queen Elizabeth Hospital

Sheriff Hill

Gateshead

England

United Kingdom

NE9 6SX

+44 (0)191 445 2155

alison.harvey@ghnt.nhs.uk

**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