

# Neck of femur Optimisation Therapy-Targeted Stroke volume

<b>Submission date</b> 29/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/12/2017	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**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**  
5165

## Study information

**Scientific Title**  
The use of LiDCO guided fluid administration in hip fracture surgery: a randomised interventional treatment trial

**Acronym**  
NOTTS

## **Study objectives**

To investigate if using a LiDCO machine (a minimally invasive device that measures how well the heart is pumping blood around the body) to guide the amount of intravenous fluid a patient gets while having their fractured hip repaired under a spinal anaesthetic affects:

1. The time the patient spends in hospital
2. The time until the patient is medically well enough to be discharged from hospital

As of 21/06/2011 the anticipated end date for this trial has been extended from 01/09/2010 to 01/08/2012.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Nottingham REC 1 approved on the 03/10/2008 (ref: 08AN004)

## **Study design**

Randomised interventional treatment trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Topic: Cardiovascular, Generic Health Relevance and Cross Cutting Themes; Subtopic: Cardiovascular (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Cardiovascular, Surgery

## **Interventions**

Optimisation of fluid balance using SV targetted boluses of intravenous gelofusine 250 ml over 5 minutes compared to a cohort group having their fluid balance according to best usual practise (i.e., at the discretion of the attending anaesthetist).

Follow up length: 1 months

Study entry: single randomisation only

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

To investigate if using a LiDCO machine (a minimally invasive device that measures how well the heart is pumping blood around the body) affects the time spent in hospital. Determined by the patients length of stay.

## **Key secondary outcome(s)**

1. To use the LiDCO machine to characterise any changes in blood pressure and the amount of blood pumped
2. To investigate if using a LiDCO machine in patients undergoing hip fracture surgery with a spinal anaesthetic
3. To characterise the changes in the way the heart and blood vessels work after a spinal anaesthetic

Outcome measures are determined by the patients length of stay. Mortality will be compared at 30, 60 and 90 days.

**Completion date**

01/08/2012

## Eligibility

**Key inclusion criteria**

1. Patients listed for surgical repair of fracture neck of femur under spinal anaesthesia
2. Aged greater than 60 years, either sex

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Key exclusion criteria**

1. Planned general anaesthetic
2. Severe valvular heart disease previously shown on echocardiography (reduces reliability of monitor measurements)
3. Taking lithium (interferes with calibration of monitor)
4. Multiple injuries requiring operative management
5. Revision surgery or total hip arthroplasty for fractured neck of femur (a different patient /surgical population)

**Date of first enrolment**

01/01/2009

**Date of final enrolment**

01/08/2012

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**  
Nottingham University Hospitals NHS Trust  
Nottingham  
United Kingdom  
NG5 1PB

## Sponsor information

**Organisation**  
Nottingham University Hospitals NHS Trust (UK)

**ROR**  
<https://ror.org/05y3qh794>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

## Results and Publications

**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?
<a href="#">Results article</a>	results	01/03/2015		Yes	No
<a href="#">Protocol article</a>	study protocol	28/09/2011		Yes	No