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Neck of femur Optimisation Therapy-Targeted Stroke volume

Submission date	Recruitment status	[_] Prospectively registered
29/04/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/12/2017	Circulatory System	

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
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 03/102008 (ref: 08AN004)

Study design
Randomised interventional treatment 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
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 measure
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.

Secondary outcome measures
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 with be compared at 30, 60 and 90 days.

Overall study start date
01/01/2009

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

Age group
Senior

Sex
Both

Target number of participants
Planned sample size: 130; UK sample size: 130

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
England

United Kingdom

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

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust (UK)

Sponsor details
City Hospital Campus
Hucknall Road
Nottingham
England
United Kingdom
NG5 1PB

Sponsor type
Hospital/treatment centre

Website
http://www.nuh.nhs.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

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?
Protocol article	study protocol	28/09/2011		Yes	No
Results article	results	01/03/2015		Yes	No