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Goal Directed Therapy (GDT) in hip replacement

Submission date
24/02/2011

Recruitment status
No longer recruiting

Registration date
18/03/2011

Overall study status
Completed

Last Edited
22/11/2011

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Prot. 2007/8/A

Study information

Scientific Title
Goal Directed Therapy (GDT) in hip replacement: a single-centre randomised controlled trial

Study objectives

Goal Directed Therapy during regional anaesthesia in primary hip arhtroplasty changes intraoperative fluid management and decreases postoperative morbidity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Direct Management Corporate University Hospital of Udine (Azienda Policlinico Universitario Gestione Diretta di Udine) approved on 12th March 2007 (ref Prot. 2007/8/A)

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Primary hip arthroplasty

Interventions
All patients will receive spinal anaesthesia was performed at the L3-L4 level with levobupivacaine 0.5% 15 mg.

CTRL group:
Patients randomised to the control group will receive Ringer lactate solution at 10 ml/kg/hour. 250 ml boluses of intra venous colloid will be administered to maintain blood pressure.

Goal Directed Therapy (GDT) group:
This group will be connected to the FloTrac/Vigileo (Edwards Lifesciences, CA, USA) haemodynamic monitoring system. Boluses of 250 ml of colloid will be administered until the stroke volume fails to further increase by a factor of 10%. If at this stage the DO2I is not greater than 600 ml/m2 then dobutamine will be started.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Intraoperative fluid management -fluid management will be recorded from the arrival to the anaesthetic room until discharge to the ward
2. Blood consumption will be recorded from arrival to the anaesthetic room until hospital discharge

Key secondary outcome(s))

Postoperative morbidity: assessed from discharge to the ward until hospital discharge by a modified postoperative morbidity survey (POMS)

Completion date
01/04/2008

Eligibility

Key inclusion criteria
Adult (>18 years old), patients undergoing primary hip arthroplasty under spinal anaesthesia

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients refusing consent
2. Patients with planned admission to intensive care unit (ICU) postoperatively
3. Patients with a contraindication to spinal anaesthesia

Date of first enrolment
01/04/2007

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
Italy

Study participating centre
Dpt of Anaesthesia and Intensive Care Medicine
Udine
Italy
33100

Sponsor information

Organisation
Clinic of Anaesthesiology and Intensive care (CareClinica di Anestesia e Rianimazione) (Italy)

Funder(s)

Funder type
University/education

Funder Name
Department of Anaesthesia and Intensive Care Medicine-University of Udine (Italy)

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?
Results article	results	01/10/2011		Yes	No
Abstract results		08/08/2008		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes