

Goal Directed Therapy (GDT) in hip replacement

Submission date 24/02/2011	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 18/03/2011	Overall study status Completed	☐ Protocol
Last Edited 22/11/2011	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ Results
		☐ 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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Contact details

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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 arthroplasty 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