# Goal Directed Therapy (GDT) in hip replacement

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
24/02/2011		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
18/03/2011	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
22/11/2011	Musculoskeletal Diseases			

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

### Contact name

Prof Giorgio Della Rocca

#### 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 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

Αll

### 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 adde	d 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 11/11/202	5 No	Yes