ISRCTN11616985 https://doi.org/10.1186/ISRCTN11616985

# 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

**Contact name**
Prof Giorgio Della Rocca

**Contact details**
Dpt of Anaesthesia and Intensive Care Medicine
of the Medical School of the University of Udine
Piazzale S. Maria della Misericordia, 15
Udine
Italy
33100
+39 (0)4 3255 9500
giorgio.dellarocca@uniud.it

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## 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
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 measure
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

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

### Overall study start date
01/04/2007

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
40

### 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)

### Sponsor details
Clinica di Anestesia e Rianimazione
AOU S. Maria della Misericordia
P.le S. Maria della Misericordia, 15
Udine
Italy
33100
+39 (0)4 3255 9501
clinicaanestesiarianimazione@aoud.sanita.fvg.it

### Sponsor type
Hospital/treatment centre

# Funder(s)

### Funder type
University/education

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

# 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? |
|---|---|---|---|---|---|
| Abstract results | | 08/08/2008 | | No | No |
| Results article | results | 01/10/2011 | | Yes | No |