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Haemodynamic protocols in traumatology

Submission date 15/06/2008	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 31/07/2008	**Overall study status** Stopped	
Last Edited 09/03/2016	**Condition category** Musculoskeletal Diseases	

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
N/A

Study information

Scientific Title

The feasability, the implementation and the influence on patient outcome of an intra-operative goal-directed haemodynamic protocol and post-operative directives in comparision to conventional treatment in cemented and uncemented hemiarthroplasty of femoral neck fractures: a pilot study

Study objectives
Primary hypothesis:
The use of an intra-operative goal-directed haemodynamic protocol and post-operative directives reduces the incidence of delirium in comparison to conventional treatment in cemented and uncemented hemiarthroplasty of femoral neck fractures.

Secondary hypothesis 1:
The use of an intra-operative goal-directed haemodynamic protocol and post-operative directives peri-operatively reduces the occurrence of pulmonary, renal and cardiovascular dysfunction and the incidence of infections and improves quality of life in comparision to conventional treatment without influence of the kind of fixation in cemented and uncemented hemiarthroplasty of femoral neck fractures.

Secondary hypothesis 2:
The use of an intra-operative goal-directed haemodynamic protocol and post-operative directives is feasible with a low rate of protocol violations to reach a high implementation rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Charité - University Medicine Berlin, 11/03/2008

Study design
Prospective randomised double-blinded two-arm single-centre 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
Hemiarthroplasty of femoral neck fractures

Interventions

1. Targeted-volume application guided by oesophageal Doppler; only during the primary operation
2. Post-operative directives versus conventional volume application; only during the time the patient is in the intensive care unit (ICU)/intermediate care unit (IMCU) to finish post-operative directives (POD) 0 on the first post-operative day one at 8 am.

The follow-up will be up hospital discharge or up to the 30th post-operative day. The patient will be contacted 90 days after the operation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Peri-operative incidence of delirium, examined the whole time during the hospital stay of the patient.

Secondary outcome measures
1. Frequency of alcohol and drug abuse in patients undergoing femoral neck repair, examined directly after inclusion of the patient in the study
2. Peri-operative incidence of pulmonary, renal and cardiovascular dysfunction and of protocol violations, examined the whole time during the hospital stay of the patient
3. Post-operative incidence of infections, examined the whole time during the hospital stay of the patient
4. Quality of life (measured using the EuroQoL instrument), examined after inclusion in the study and 90 days after the operation

Overall study start date
15/06/2008

Completion date
30/12/2011

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Aged greater than or equal to 60 years, either sex
2. Written informed consent of the patient
3. Anamnestically two or more years post-menopausal or surgically sterile
4. Patients with dislocated femoral neck fracture which is not older than 24 hours and will be operated within the next 24 hours

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Aged less than 60 years
2. No written consent from patient
3. Inability to communicate safely in German
4. Unwillingness to allow storage and sharing of anonymised disease data in the context of the clinical study
5. Simultaneous participation of the patient in another study or having been in a study which was terminated less than one month ago and not planned within the next three months
6. Accommodation in an institution due to an official or judicial order
7. Members of staff of the Charité
8. Advanced disease of the oesophagus of nasopharyngeal cavity
9. Operations in the area of the oesophagus or nasopharynx within the last two months
10. Liver disease (Child B or C cirrhosis, End-Stage Liver Disease [MELD] score greater than 10)
11. Condition after acute or chronic pancreatitis
12. History of bleeding tendency
13. Von Willebrands disease
14. Neurological or psychiatric disease
15. Chronic heart failure New York Heart Association (NYHA) class IV
16. American Society of Anaesthesiologists (ASA) classification greater than III
17. Renal failure (serum creatinine greater than 2.0 mg/dl or greater than 150 µmol/l or dependency of haemodialysis)
18. Existence of a pulmonary oedema in the preoperative chest x-ray
19. Allergy to hydroxyethyl starch or other ingredients of the intravenous solutions
20. History of intracranial haemorrhage within one year

Date of first enrolment
15/06/2008

Date of final enrolment
30/12/2011

Locations

Countries of recruitment
Germany

Study participating centre

Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin)
Berlin
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Sponsor information

Organisation
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

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Sponsor type
University/education

Website
http://www.charite.de/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
University/education

Funder Name
Charité Universitätsmedizin Berlin

Alternative Name(s)
Medical School - Charité - University Medicine Berlin

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

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