

Haemodynamic protocols in traumatology

Submission date 15/06/2008	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 31/07/2008	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 09/03/2016	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Claudia Spies

Contact details
Charitéplatz 1
Berlin
Germany
10117
+49 (0)30 450 55 10 01
claudia.spies@charite.de

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

The feasibility, the implementation and the influence on patient outcome of an intra-operative goal-directed haemodynamic protocol and post-operative directives in comparison 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 comparison 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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 or 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 Willebrand's 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

Germany

10117

Sponsor information

Organisation

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration