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Randomised controlled trial on risk adapted damage control orthopaedic surgery of femur shaft fractures in multiple trauma patients

Submission date
05/01/2007

Recruitment status
No longer recruiting

Registration date
09/02/2007

Overall study status
Completed

Last Edited
13/10/2016

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2.0 - 07/11/2006

Study information

Scientific Title
Randomised controlled trial on risk adapted damage control orthopaedic surgery of femur shaft fractures in multiple trauma patients

Study objectives
Primary reamed nailing of femoral shaft fracture versus temporary fixation with fixateur externe and secondary reamed intramedullary nailing (not earlier than 48 hours after trauma) are different in maximum Sepsis-related Organ Failure (SOFA) score within four weeks after trauma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Cologne, 13/11/2006, ref: 02-109

Study design
Randomised controlled trial without blinding

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Multiple trauma (including femoral shaft fracture)

Interventions
Experimental intervention:
Temporary fixation with fixateur externe and secondary reamed intramedullary nailing not earlier than 48 hours after trauma.

Control intervention:
Primary reamed nailing of femoral shaft fracture.

Intervention Type

Procedure/Surgery

Primary outcome measure
Maximum SOFA Score within 4 weeks after trauma

Secondary outcome measures
1. Hospital mortality
2. Cumulative organ failure = sum of SOFA score points for the first 28 days
3. Acute Respiratory Distress Syndrome (ARDS) incidence
4. Systemic Inflammatory Response Syndrome (SIRS) and sepsis incidence during Intensive Care Unit (ICU) stay
5. Quantity and duration of surgical interventions, anaesthetics and costs of surgery (material, time)
6. Length of ICU stay, number of ventilator free days
7. Therapeutic Intervention Scoring System (TISS) 28 during ICU (costs)
8. Rate of phlegmona of the medullary cavity
9. Patient rate in which conversion to internal fixation was not possible
10. Rate of pseudarthrosis
11. Functional outcome at discharge, six and 12 months after trauma
12. Quality of life at discharge, six and 12 months after trauma (determined by Polytrauma Outcome [POLO] chart)
13. Glasgow Outcome Scale (GOS) at discharge, six and 12 months after trauma
14. Length of hospital stay
15. Length of inability to work

Overall study start date
01/04/2007

Completion date
01/04/2009

Eligibility

Key inclusion criteria
1. Multiple trauma (injury of at least two body regions)
2. Injury Severity Score (ISS) more than 16
3. Femoral shaft fracture which can be treated in principle by nail or fixateur externe
4. Beginning of surgical treatment within 24 hours after trauma
5. Patient aged 18 years and older
6. Calculated probability of death between 20% and 60%
7. All factors known which are needed for the calculation of probability of death (age, ISS, Glasgow Coma Score [GCS], base excess, quick)

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
140

Key exclusion criteria
1. III° open fractures
2. Endangerment of the patient by one of the both strategies
3. Refusal of one of both strategies by either the investigator or the patient
4. Start of internal or external fracture fixation before randomisation
5. Participation in concurrent interventional trials
6. Pregnancy

Date of first enrolment
01/04/2007

Date of final enrolment
01/04/2009

Locations

Countries of recruitment
Germany

Study participating centre
University of Witten/Herdecke
Cologne
Germany
51109

Sponsor information

Organisation
Private University of Witten/Herdecke gGmbH (Germany)

Sponsor details
Alfred-Herrhausen-Str. 50
Witten
Germany
58448

Sponsor type

University/education

Website
http://www.uni-wh.de/

ROR
https://ror.org/00yq55g44

Funder(s)

Funder type
Government

Funder Name
Deutsche Forschungsgemeinschaft (Germany) (ref: DFG RI 929/3-1)

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/08/2009		Yes	No

Results article	results	25/01/2016	Yes	No