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Treatment of incomplete burst fractures (AO Type A3.1) with dorsal or dorso-ventral proceeding

Submission date	Recruitment status	[ ] Prospectively registered
24/01/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/03/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/03/2011	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Randomised controlled trial for treatment of incomplete burst fractures (AO Type A3.1) with dorsal or dorso-ventral proceeding

Acronym
A3.1

Study objectives
The objective of the study:
1.To compare different operative (OP) methods with each other
1.1.Minimal clinical relevant difference for Visual Analogue Scale (VAS) within 5 points and 10 points
1.2. Minimal clinical relevant difference for bisegmental ground cover plate angle (GDW) 5 grade

Study options:
1. Dorsal mono/bisegmental vs. ventral monosegmental
2. Dorsal mono/bisegmental vs. dorso-ventral
3. Dorsal mono/bisegmental vs. conservative

The dorso-ventral stabilisation will give better radiological results than isolated dorsal stabilisation (follow-up 2 years)
The dorso-ventral stabilisation will receive the same results as the isolated dorsal stabilisation (follow-up 2 years)
The dorso-ventral stabilisation will receive better radiological results than the isolated dorsal stabilisation (follow-up 5 years)
The dorso-ventral stabilisation receives better results than the isolated dorsal stabilisation (follow-up 5 years)
The rate of revisions is each dorso-ventral stabilisations less than the rate after isolated dorsal stabilisations (follow-up 5 years)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Commission in the Hessen State Medical Association (Ethikkommission bei der Landesärztekammer Hessen), approved on 07.07.2010, reference number: FF23/2010

Study design
Single-centre prospective randomised controlled case-control-trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
A3.1 burst fracture

Interventions
Dorsal or dorso-ventral stabilisation of spine fractures

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Pre OP:
1.1. Oswestry Disablity Index
1.2. EQ-5D
1.3. VAS
1.4. Intake of analgesics
1.5. VAS-Spine Score
2. Post OP 3 months/12 months/24 months :
2.1. Oswestry Disablity Index,
2.2. EQ-5D
2.3. VAS
2.4. Intake of analgesics
2.5. VAS-Spine Score
2.6. Odom's criteria

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/09/2012

Eligibility

Key inclusion criteria
1. Age between 18 and 60 years
2. Fracture type A3.1.1
3. Localisation Th11 L3
4.Mono-injury

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Systemic diseases for example rheumatic diseases,human immunodeficiency virus (HIV), acquired immunodeficiency syndrome (AIDS), tumor, ankolysing sponylitis (M. Bechterew), etc
2. Osteoporosis (T-Score less than minus 2.5)
3. Polytrauma, multiocular spine injuries
4. No ventral OP possible, pulmonary diseases, obesity (adipositas), already ventral surgery received, etc
5. For study option 2
5.1. Neurologic deficit after spine surgery]

Date of first enrolment
01/09/2009

Date of final enrolment
01/09/2012

Locations

Countries of recruitment
Germany

Study participating centre
Zentrum für Wirbelsäulenchirurgie und Neurotraumatologie
Frankfurt am Main
Germany
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Sponsor information

Organisation
Centre for Spinal Surgery and Brain Trauma (Zentrum für Wirbelsäulenchirurgie und Neurotraumatologie) Germany

ROR
https://ror.org/04kt7f841

Funder(s)

Funder type
Government

Funder Name

Centre for Spinal Surgery and Brain Trauma (Zentrum für Wirbelsäulenchirurgie und Neurotraumatologie) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration