

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

Submission date 24/01/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/03/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/03/2011	Condition category Injury, Occupational Diseases, Poisoning	<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

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Additional identifiers

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 Disability 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 Disability 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, ankylosing spondylitis (M. Bechterew), etc

2. Osteoporosis (T-Score less than minus 2.5)
3. Polytrauma, multicolar 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

60389

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