

The optimal treatment of odontoid fractures in the elderly: A prospective study.

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Odontoid fractures are the most common cervical spine fractures in the elderly. However, the optimal treatment of this condition is still subject to controversy. The goal of this study is to assess fracture union/stability and clinical outcome after...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON25295

Source

NTR

Brief title

INNOVATE Trial

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym

Dens fractures

Health condition

Odontoid fractures in the elderly

Research involving

Human

Sponsors and support

Primary sponsor: Leiden University Medical Center, Leiden, The Netherlands

Source(s) of monetary or material Support: EuroSpine

Intervention

Outcome measures

Primary outcome

1. Osseous union;
2. Fracture stability;
3. Clinical outcome (NDI).

Secondary outcome

1. MDI;
2. VAS neck pain score;
3. SF-36;
4. EQ5D;
5. DS14;
6. IPQ-K;
7. Fracture gap;
8. Fracture angulation;
9. Grade of osteoporosis in C2;
10. Grading of degeneration in C0-C2 joints;
11. Complications;
12. Secondary interventions.

Study description

Background summary

Patients meeting the inclusion criteria will be asked to participate. The treatment will be based on the treating surgeon's preference and can be either surgical or conservative. The goal of this study is to assess fracture union/stability and clinical outcome after the different treatments. Seventeen centres from eight different countries have agreed to participate (The Netherlands, Austria, Germany, Spain, United Kingdom, Sweden, Belgium, Italy).

Study objective

Odontoid fractures are the most common cervical spine fractures in the elderly. However, the optimal treatment of this condition is still subject to controversy. The goal of this study is to assess fracture union/stability and clinical outcome after surgical and conservative treatments for odontoid fractures in the elderly.

Study design

Follow-up moments are scheduled at 6, 12, 26, 52 and 104 weeks after the start of treatment.

Intervention

1. Surgical treatment (anterior odontoid screw fixation or posterior cervical fusion);
2. Conservative treatment (cervical collar or halo traction).

Contacts

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Eligibility criteria

Age

Adults (18-64 years)

Adults (18-64 years)

Elderly (65 years and older)

Elderly (65 years and older)

Inclusion criteria

11-04-2013: New inclusion criteria: 1. ≥ 55 years old;

2. Acute type II or III odontoid fracture according to Anderson and d'Alonzo classification (possibly in combination with other fractures); diagnosed using CT;

3. Less than two weeks after injury;

4. Informed consent.

Exclusion criteria

11-04-2013: New exclusion criteria: 1. Rheumatoid arthritis;

2. Ankylosing spondylitis;

3. Previous treatment for odontoid fracture;

4. Communication with patient is hampered (e.g. language barrier, severe cognitive impairment, coma).

Study design

Design

Study phase: N/A

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2012
Enrollment:	275
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO	
Date:	23-08-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 50404
 Bron: ToetsingOnline
 Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3337
NTR-old	NTR3630
CCMO	NL39744.058.12
OMON	NL-OMON50404

Study results

Summary results

N/A