Surgical versus conservative treatment of odontoid fractures in the elderly: a prospective cohort study

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

Summary

ID

NL-OMON50404

Source
ToetsingOnline

Brief title
INNOVATE Trial

Condition

- Nervous system, skull and spine therapeutic procedures

Synonym
dens fracture, Fractured odontoid process

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Financiering gevraagd bij Eurospine;indien afgewezen uit afdelingsfonds (1e geldstroom)

Intervention

Keyword: Elderly, Odontoid fractures, Optimal treatment, Prospective study

Outcome measures

Primary outcome

- Clinical outcome, scored by the Neck Disability Index at 52 weeks after start of treatment

- Fracture healing, assessing union (union or non-union) and stability at 52 weeks after start of treatment

Union will be defined by evidence of bone trabeculae crossing the fracture site and absence of sclerotic borders adjacent to the fracture site, assessed using computed tomography (CT).

Fracture stability will be assessed using cervical dynamic X-rays in lateral projection. A maximum of 2 mm movement at the fracture site is considered stable.

Imaging data will be sent to the coordinating centre and will be judged by independent assessors (neuroradiologists) who are blinded to the results.

Secondary outcome

Clinical: Myelopathy Disability Index, VAS neck pain score, SF-36, EQ5D, DS14 (psychometric properties), IPQ-K (illness perception), Likert

Radiological: Fracture displacement, grade of osteoporosis in C2, grade of degeneration of C1-C2 facet joints, pseudoarthrosis

General: Complications, reinterventions (secondary surgery, surgery after

failed conservative treatment)

Study description

Background summary

Odontoid fractures are the most common cervical spine injuries in elderly patients and their prevalence is expected to increase. The choice between surgical or conservative treatment for patients of this age group is still controversial. No consensus exists as to whether the goal of treatment should be osseous union, fracture stability or clinical outcome and how outcome should be measured. A recent review of the available literature could not yet identify the optimal treatment.

Study objective

The goal of this prospective cohort study is to assess fracture union/stability and clinical outcome after surgical and conservative treatments of type II/III odontoid fractures in the elderly patient (>=55 years). The general presumption is that a surgical intervention is generally technically successful, since it leads to a stable cervical spine. However, the condition of the patient may deteriorate through undergoing cervical spine surgery. Therefore, especially in the very old patient (>=80 years of age) a conservative treatment is often proposed to avoid the complications that may accompany spine surgery. This may lead to non-union, but if the cervical spine is stable, this does not necessarily lead to secondary surgery. The outcome parameter, union, that is often used in literature, may thus not accurately reflect the clinical situation and its consequences. Debate remains as to whether non-union can lead to complaints in the patient.
A study in which the clinical condition of both surgically and conservatively treated patients is well monitored, as well as their radiological condition, both reviewing union and stability, may lead to better decisions in odontoid fractures in the elderly. Ideally the subgroup analysis may offer prognostic factors that can predict the success of either a surgical or conservative treatment.

Study design

A prospective, comparative cohort study with two parallel groups is to be carried out. Patients suffering from acute type II and III odontoid fractures and who are over 55 years of age will be included. A multicenter study is necessary to include the required number of patients in the proposed time

frame. All participating hospitals are individually responsible for the treatment applied. At admission and follow-up moments, patients will be seen by their treating physician.
Based on the treating surgeon*s decision, surgical or conservative treatment will be started and documented. During follow-up appointments, demographic, radiological and clinical data will be gathered. Patients will also be sent questionnaires to complete at home. Questionnaires will focus on pain intensity, general wellbeing, perceived recovery and illness-related inconveniences.

Study burden and risks

Participating in the study will not pose additional risks. Patients will be askes to complete questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- At least 55 years old
- Acute type II and III odontoid fracture according to Anderson and d*Alonzo classification (possibly in combination with other fractures); diagnosed using computed tomography
- Less than two weeks after injury
- Informed consent

Exclusion criteria

- Rheumatoid arthritis
- Ankylosing spondylitis
- Previous treatment for odontoid fracture
- Communication with patient is hampered (e.g. language barrier, severe cognitive impairment, coma)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-10-2012
Enrollment:	120
Type:	Actual

Ethics review

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

Approved WMO Date:	07-11-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	19-12-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	01-05-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-09-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	15-04-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO Date:	11-05-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	23-06-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	24-11-2020
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 25295
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL39744.058.12
OMON	NL-OMON25295

Study results

Date completed: 21-02-2023

Actual enrolment: 152

Summary results
Trial is onging in other countries