

# Complication Of Osteoporosis in Spinal cord injury

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To collect data regarding the prevalence of:I) - osteoporosis in SCI patients and the relation to characteristics of SCI. - fractures in SCI patients and the relation to characteristics of SCI. - active treatment of osteoporosis in SCI patients.II...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Hypothalamus and pituitary gland disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON30685

### Source

ToetsingOnline

### Brief title

COOS

### Condition

- Hypothalamus and pituitary gland disorders
- Fractures
- Spinal cord and nerve root disorders

### Synonym

low bone density, Paraplegia

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Indien het recent opgerichte Dwarslaesie Fonds over voldoende financiële middelen beschikt (of gaat beschikken);zal hieruit (een deel

van) het onderzoek gefinancierd worden. Verder zullen deze hoog-risico dwarslaesiepatiënten in het kader van case finding zoals beschreven in de CBO Richtlijn Osteoporose 2002;op consultbasis gezien worden. De ziektenkostenverzekering vergoedt dus de kosten aangezien het onderzoek op osteoporose bij deze patiënten feitelijk onder normale patiëntenzorg valt.

## Intervention

**Keyword:** Epidemiology, Fractures, Osteoporosis, Spinal cord injury

## Outcome measures

### Primary outcome

1. Absolute and relative number of patients with diagnosis of osteoporosis

according to

- a. WHO criteria: T-score lower or equal than -2.5
- b. BMD at the femoral neck of 0.577 g/cm<sup>2</sup> or less.

2. Absolute and relative number of patients with diagnosis of osteopenia

according to WHO criteria: T-score lower or equal than -1.0 and higher than \*2.5

3. Absolute and relative number of patients with fractures after the onset of

SCI.

4. Absolute and relative number of patients with adequate treatment for osteoporosis or osteopenia with fractures.

### Secondary outcome

5. Proportion of patients with high bone turnover.

6. Total Qol-score.

7. Proportion of patients with endocrine disturbances.

8. Proportion of patients with autonomic dysregulation.

## Study description

### Background summary

The Netherlands has approximately 16.000 spinal cord injury patients. Spinal cord injury (SCI) is often associated severe osteoporosis. Osteoporosis has a prevalence of approximately 60% in men with SCI. Osteopenia is seen in 20% and fractures occur in 20 to 35% of patients. Despite this high prevalence, patients are not usually analyzed for the presence of osteoporosis. Recent studies point towards an important role of the autonomic nervous system in the pathogenesis of osteoporosis and this might be of extra interest and importance in SCI patients. Endocrine disturbances as seen in traumatic brain injury might be a contributing factor when also present. Most importantly, there are no guidelines for diagnosis and treatment of osteoporosis in SCI patients.

Hypothesis:

- A) Osteoporosis is common in patients with SCI and often causes fractures.
- B) Osteoporosis in patients with SCI is undertreated.
- C) Besides immobilization, other (endocrine) disturbances such as hypogonadism and/or growth hormone deficiency, which are seen after SCI with accompanying Traumatic Brain Injury (TBI) might also aggravate loss of BMD.
- D) SCI results in an increased loss of BMD of more than 1 SD compared to the normal population.
- E) The decentralized autonomic nervous system with periodic high sympathetic activity (often seen in SCI patients), might be related to the frequency of occurrence and severity of osteoporosis. In line with this we hypothesize that anti-beta-adrenergic blockade might be protective.

### Study objective

To collect data regarding the prevalence of:

- I) - osteoporosis in SCI patients and the relation to characteristics of SCI.
- fractures in SCI patients and the relation to characteristics of SCI.
- active treatment of osteoporosis in SCI patients.
- II) - hormonal abnormalities (as seen in TBI) in SCI patients.

To compare:

III) - BMD of SCI patients to BMD of control groups:  
> BMD of brother, sister or partner of SCI patient.  
> AGGO-database (ages: between 30-42 years old).  
> LASA-database (ages: 55 years or older).

To investigate a possible relation between:

IV) - the sympathetic and parasympathetic nervous system activity and/or endocrine disturbances and BMD.

V) - fractures and Quality of Life (QoL).

## **Study design**

Cross sectional, monocenter, single country, observational study.

## **Study burden and risks**

This is an epidemiological study in which patients from the rehabilitation center are referred to the outpatients clinic of the department of endocrinology of the VU University Medical Center for an intake and physical examination (including blood pressure while, lying, sitting and when possible standing), blood and urine investigations. Also, a total body, lumbar and femoral bone mineral density measurement (DXA) will be done, combined with an Instant Vertebral Assessment (IVA) for diagnosis vertebral fractures. If indicated, conventional X-rays can be done of specified skeletal parts. Radiation dosages of DXA/IVA are very low. Heart rate-variance will be measured with a 24 hour ambulant recording. These investigations will take 3 visits after which a treatment advice is given.

## **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

- Male or female persons with spinal cord injury
- Age from 18 to 70 years
- SCI since > 1 year

### Exclusion criteria

- Inability to give informed consent

## 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:	Pending

Start date (anticipated):	01-02-2007
Enrollment:	80
Type:	Anticipated

## Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

### In other registers

Register	ID
CCMO	NL15360.029.06