Observational study; Osteoporosis in spinal cord injury patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25800

Source
NTR

Brief title
COOS

Health condition

1. Spinal Cord Injury;

2. Osteoporosis;

3. Fractures.

(NLD: Dwarslaesie, osteoporose, botonkalking, fracturen, botbreuken).

Sponsors and support

Primary sponsor: Investigator-driven: Department of Endocrinology, VU University Medical Center.
Source(s) of monetary or material Support: Department of Endocrinology, VU University Medical Center.

Intervention

Outcome measures

Primary outcome

1. Absolute and relative number of patients with diagnosis of osteoporosis or osteopenia according to WHO criteria;

2. Proportion of participants with a Z-score of -1.0 or lower;

3. Absolute and relative number of patients with fractures after the onset of SCI and the proportion that is adequately treated.

Secondary outcome

1. Proportion of patients with high bone turnover;

2. Total Qol-score;

3. Proportion of patients with endocrine disturbances and/or autonomic dysregulation.

Study description

Background summary

Spinal cord injury (SCI) is a major risk factor for osteoporosis due to immobilization. Limited data suggest that osteoporosis has a prevalence of approximately 60-80% in men with SCI and fractures occur in 20 to 35% of patients. Despite this high prevalence, patients are not usually analyzed for the presence of osteoporosis and data on prevalence and incidence of osteoporosis and fractures are limited and although bisphosphonates have been shown to be effective in reducing bone loss after acute SCI, chronic SCI is not seen as an indication for secondary prevention with antiosteoporotic medication.

This study aims to determine prevalence of osteoporosis, fractures and active treatment in patients with SCI since more than 1 year. Also we will investigate other possible pathophysiologic processes as accompanying traumatic brain injury or autonomic dysfunction, that might contribute to the high bone loss in SCI.
It is a 2-year monocenter, cross sectional observational study in which 40 wheelchair-bound patients with traumatic SCI since more than 1 year and 40 healthy controls will be investigated for osteoporosis according to WHO-criteria. Data regarding fractures, quality of life, level, completeness and duration of SCI will be collected. In case of traumatic brain injury pituitary hormone levels will be measured. Autonomic (dys)function will be investigated. After

completion of the study, participants will receive a treatment advice.

Study objective

Osteoporosis is common in patients with SCI and often causes fractures and is undertreated.

Besides immobilization, other (endocrine) disturbances such as hypogonadism and/or growthhormone deficiency, which are seen after SCI with accompanying Traumatic Brain Injury (TBI) might also aggravate loss of BMD. Also, 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.

Study design

N/A

Intervention

None. Observational study in 40 spinal cord injury patients and 40 healthy controls.

Contacts

Public
VU University Medical Center.
Department Endocrinology
P.O. Box 7057

B.L.J Kanen
Amsterdam 1007 MB
The Netherlands
020-4440530
Scientific
VU University Medical Center.
Department Endocrinology
P.O. Box 7057

B.L.J Kanen
Amsterdam 1007 MB
The Netherlands
020-4440530

Eligibility criteria

Inclusion criteria

1. Wheelchair-bound male or female persons with spinal cord injury;

2. Age from 18 to 70 years;

3. SCI since > 1 year.

Exclusion criteria

Inability to give informed consent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2007
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-11-2007
Application type:	First submission

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
NTR-new	NL1109
NTR-old	NTR1145
Other	VU University Medical Center : protocol ID/number 2007/006
ISRCTN	ISRCTN wordt niet aangevraagd/Observational study

Study results

Summary results
N/A