Observational study; Osteoporosis in spinal cord injury patients.

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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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25800

Bron
Nationaal Trial Register

Verkorte titel
COOS

Aandoening

1. Spinal Cord Injury;

2. Osteoporosis;

3. Fractures.

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

Ondersteuning

Primaire sponsor: Investigator-driven: Department of Endocrinology, VU University Medical Center.
Overige ondersteuning: Department of Endocrinology, VU University Medical Center.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

2. Age from 18 to 70 years;

3. SCI since > 1 year.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Inability to give informed consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2007
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-11-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A