Long-term secondary health conditions, fitness and active lifestyle in persons with spinal cord injury for at least ten years.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Observational invasive

Summary

ID

NL-OMON36054

Source
ToetsingOnline

Brief title
Long-term health conditions, fitness and active lifestyle after SCI.

Condition

- Spinal cord and nerve root disorders

Synonym
Spinal cord injury, traumatic myelopathy

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum De Hoogstraat

Source(s) of monetary or material Support: ZonMw; Fonds Nuts Ohra

Intervention

Keyword: Active lifestyle, Fitness, Secondary health conditions, Spinal cord injury

Outcome measures

Primary outcome

The overall aim of this study is to assess the prevalence of long-term secondary health conditions in persons with SCI for at least ten years.

The secondary health conditions that will be evaluated are: bladder- and bowel disorders, pressure sores, spasticity, sexual function deficits, cardiovascular diseases, respiratory problems and (chronic) pain. A comprehensive anamneses (including spirometry and blood pressure measurement) on these secondary conditions will be performed. In addition, self-report measures on specific secondary health conditions will be administered in a mailed questionnaire.

Secondary outcome

The main secondary parameters are related to the impact of the long-term secondary health conditions and poor fitness on quality of life. For this the degree of active lifestyle, activity limitations, participation, (wheeled) fitness and overall well-being will be measured (components of the concept *quality of life*).

• Active lifestyle will be measured with the Physical Activity Scale for Individuals with Physical Disabilities (PASIPD).

• Activity limitations will be evaluated with two measures: the Spinal Cord Independence Measure version III (SCIM-III) for defining limitations in

self-care and mobility and the Wheelchair circuit for assessing wheelchair skills/capacity.

• Participation will be measured with the Utrecht Scale for Evaluation of Rehabilitation-Participation (USER-P).

• Fitness is measured with the wheelchair submaximal and maximal exercise test.

• Fatigue will be measured with the Fatigue Severity Scale (FSS).

• Mood will be measured with the Mental Health Inventory-5 (MHI-5).

• Overall well-being will be measured with the World Health Organization Quality of Life-5 (WHOQOL-5).

Study description

Background summary

Many individuals with long-term spinal cord injury (SCI) show, according to the literature, a serious inactive lifestyle, associated with poor fitness and secondary health conditions (e.g. bladder- and bowel disorders, pressure sores, upper-extremity pain, obesity, diabetes, respiratory problems and cardiovascular disease). This all results in reduced participation and quality of life. Avoiding this downward spiral, that threatens persons aging with SCI, is crucial.

International clinical guidelines (Consortium Spinal Cord Medicine) support long-term follow-up of persons with SCI, but this is not regular practice in the Netherlands. No systematic Dutch rehabilitation aftercare system with regular check-ups is operational.

To make the first steps towards the design of a structured and regular rehabilitation aftercare system for persons with long-term SCI in the Netherlands we have got to understand the underlying processes of de-conditioning and secondary health conditions. That will help us to define the components of a rehabilitation aftercare system that covers the lifespan and preserve functioning of persons with long-term SCI.

Study objective

1) To study the prevalence of secondary health conditions in persons with long-term SCI. It is hypothesized that longer duration of injury is associated with a higher prevalence of secondary health conditions.

2) To explore the impact of secondary health conditions on active lifestyle, fitness, participation and overall well-being in persons with long-term SCI. It is hypothesized that people with more severe secondary health conditions will show a less active lifestyle and lower levels of participation, fitness and well-being.

Study design

This will be a time since injury (TSI)-stratified cross-sectional study among 300 persons with long-term SCI. Strata of TSI will be 10-20 years, 20-30 years and more than 30 years after SCI.

This study will consist of a single aftercare check-up which will consist of anamnesis and physical examination by a rehabilitation physician, an interview by a research assistant, exercise and laboratory testing, rest-ECG, spirometry and imaging of the bladder and kidneys by an ultrasound. All these parts of the study will only take place once.

Eight Dutch rehabilitation centers (RC*s) with a SCI unit will participate in this study.

Study burden and risks

Participants may experience local upper extremity discomfort during the exercise test. The risks during the test are relatively low because of thorough screening prior to participation, monitoring possible complaints during testing and safety precautions throughout testing.
Cardiovascular contra-indications for exercise testing will be evaluated for each participant according to the American College of Sports Medicine guidelines. Persons with cardiovascular contra-indications will not participate in the exercise test.
The identification of persons with long-term SCI suffering from secondary complications and/or de-conditioning allows us to refer these persons to other health professionals of to keep them in consultation. This may benefit these persons for the long-term by receiving new or modified treatment.
The expected beneficial effects for the study population in the long-term in combination with the very limited risks would justify the execution of the purposed study.

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

• Spinal cord injury;
• Age between 28-65 years;
• Age at injury between 18 and 35 years;
• Time since injury: at least 10 years;
• Wheelchair dependent (hand rim propelled wheelchair or electric wheelchair), at least for longer distances;

Exclusion criteria

Overall exclusion criterion:
• Insufficient mastery of the Dutch language to respond to an oral interview and test

instructions.;Exclusion criteria for participation in the exercise test:
- cardiovascular comorbidity: in accordance with the guidelines of the American College of Sports Medicine (ACSM) (see our research protocol).
- Temporary contra-indications: decubitus or an infection with fever.
- Bloodpressure: diastolic bloodpressure at rest > 90 mmHg or a systolic bloodpressure at rest > 180 mmHg.
- Serious musculoskeletal complaints of the upper extremities, neck or back.
- rest-ECG abnormalities:
P wave:
o Left atrial enlargement: negative portion of the P wave in lead V1 >= 0.1mV in depth and >= 0.04s in duration;
o Right atrial enlargement: peaked P wave in leads II and III or V1 >= 0.25mV in amplitude.
QRS complex:
o Frontal plane axis deviation: right >= + 120° or left -30° to -90°;
o Increased voltage: amplitude of R or S wave in a standard lead >= 2mV, S wave in lead V1 or V2 >= 3mV, or R wave in lead V5 or V6 >= 3mV;
o Abnormal Q waves >= 0.04s in duration or >= 25% of the height of the ensuing R wave or QS pattern in two or more leads;
o Right or left bundle branch block with QRS duration >= 0.12s;
o R or R* wave in lead V1 >= 0.5mV in amplitude and R/S ratio >= 1.
ST-segment, T-waves, and QT interval:
o ST-segment depression or T-wave flattening or inversion in two or more leads;
o Prolongation of heart rate corrected QT interval >= 0.44s in males and > 0.46s in females.
Rhythm and conduction abnormalities:
o More than one premature ventricular beat or more severe ventricular arrhythmias;
o Supraventricular tachycardias, atrial flutter, or atrial fibrillation;
o Short PR interval (< 0.12s) with or without *delta* wave;
o Sinus bradycardia with resting heart rate <= 40 beats/min;
o First (PR >= 0.21s), second or third degree atrioventricular block.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-11-2011
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	09-09-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL36394.041.11