Characterisation of the immune response after spinal cord injury

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

Summary

ID

NL-OMON55320

Source
ToetsingOnline

Brief title
The immune response after spinal cord injury

Condition

- Spinal cord and nerve root disorders

Synonym
Spinal cord injury

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Hasselt
Source(s) of monetary or material Support: Wings For Life Foundation;Onderzoeksbeurs Universiteit Hasselt

Intervention

Keyword: Autoantibodies, Autoimmune response, Neuroscience, Spinal cord injury

Outcome measures

Primary outcome

- Identification of the autoantibodies produced after SCI.

- Characterisation of the autoantibody response after SCI in patients over time.

- Assessment of the association between clinical outcome parameters and changes in antibody levels: determining the prognostic biomarker potential of the candidate biomarkers.

Secondary outcome

- Determine immune cell subtypes and function, immune derivatives, inflammatory and neurological markers in peripheral blood at multiple time points following spinal cord injury.

- Assessment of the association between the clinical outcome parameters and the changes in immunological and neurological parameters in SCI patients.

Study description

Background summary

Worldwide, about 250,000 people suffer from a traumatic spinal cord injury (SCI) each year. Inflammation plays an important role in the secondary injury phase, that is characterized by further tissue degeneration. The immune response following SCI has not been studied in humans. Therefore, the aim of this project is to characterize the immune response following traumatic SCI. On the one hand, the blood immune cell profile, inflammation and neurodegeneration markers and immune derivatives will be measured. This will result in an improved insight into the cellular immune response following SCI. On the other hand, we will identify novel SCI-induced antibody biomarkers using a high-throughput autoantibody profiling approach and further characterize these

novel markers. These antibody biomarkers will support the prediction of the disease course following a traumatic SCI.

Study objective

This project focuses on the characterization of the immune response following a traumatic SCI. As individual components of the immune response work in close collaboration and have a strong influence on each other, it is important to obtain a very detailed and elaborate overview of the immune response. Therefore we will examine different aspects of the immune response in this project. Hereby, autoantibodies, immune cell populations, immune components, inflammatory and neurodegeneration markers will be investigated.

Study design

Longitudinal study

Study burden and risks

The risks are low. The risks of a blood donation are a temporary vasovagal reaction or a local haematoma at the site of the puncture.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age >= 18 years
- Recently diagnosed with SCI, i.e. not more than 8 weeks prior to admission to the rehabilitation center

Exclusion criteria

- Incapacitated patients
- Patients with pre-existing autoimmune disorders
- Patients who receive anti-inflammatory or immune modulatory treatment (e.g. corticosteroid administration)

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	24-05-2022
Enrollment:	102
Type:	Actual

Ethics review

Approved WMO Date:	13-10-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL72014.068.20
Other	NL8803 bij www.trialregister.nl