Study of the immune system following spinal cord injury

No registrations found.

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

Summary

ID

NL-OMON26426

Source Nationaal Trial Register

Brief title SCADE

Health condition

Spinal cord injury

Sponsors and support

Primary sponsor: Not applicable **Source(s) of monetary or material Support:** Wings for Life Foundation, research grant Hasselt University

Intervention

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

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 objective

The peripheral immune response is changed following a traumatic spinal cord injury.

Study design

- 1. Admission in the rehabilitation center
- 2. 3 weeks after spinal cord injury (SCI)
- 3. 6 weeks after SCI
- 4. 12 weeks after SCI
- 5. 6 months after SCI
- 6. 1 year after SCI

Contacts

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Eligibility criteria

Inclusion criteria

- Individuals older than 18 years
- Diagnosis of spinal cord injury.

Exclusion criteria

- Individuals with pre-existing autoimmune diseases
- Use of anti-inflammatory or immune modulatory treatment.

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:	Pending
Start date (anticipated):	01-09-2020
Enrollment:	102
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date: Application type:

03-06-2020 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	NL8803
Other	METC azM/UM : not known yet

Study results