PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Spinal cord injury-induced immude deficiency Syndrome: Natuarl killer (NK) cell functionality after spinal cord injury

Trial Acronym

SCI-IDS: NK cells function

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of this study is to investigate the function of Natural Killer (NK) cells at different time Points after spinal cord injury (SCI), especially during the chronic phase. NK cells are a class of lymphocytes responsible for the first line immune defense against a various range of infectious agents. Our working hypothesis is that not a deficit in immune cell numbers, but rather a deficit in cell function might be responsible for the increased susceptibility to infectious diseases after SCI. In this study we recruit patients at different time points after a traumatic spinal cord injury or traumatic vertebral fractures with the purpose of testing their NK cell function through well established immunological functional assays and compare to the one of healthy controls. The aim is to inquire whether a NK cell functional deficit might be hold responsible for the increased susceptibility of SCI patients to develop infectious diseases, the leading cause of death throughout the postacute and chronic Phase posterior to SCI.

Brief Summary in Scientific Language

Natural killer (NK) cells are the main components of lymphocyte-mediated nonspecific immunity. Through their effector function they play a crucial role combating bacterial and viral challenges. They are also thought to be key contributors to the spinal cord injury-induced immune-deficiency syndrome (SCI-IDS). SCI-IDS increases susceptibility to infection and extends to the post-acute and chronic phases after SCI.
The prognostic study of NK cell function after traumatic SCI will be carried out in two centers in Berlin, Germany. 23 SCI patients and 13 control patients with neurologically silent vertebral fracture also undergoing surgical stabilization will be enrolled in order to determine the effect of surgical stress alone. Healthy controls will be included to provide reference data. The natural killer cell function will be assessed at 7 and 14 days, as well as 10 weeks post-trauma (post-acute - chronic SCI). Clinical documentation is to include the American Spinal Injury Association (ASIA) impairment scale (AIS), neurological level of injury, infection status, concomitant injury, and medications. The primary endpoint of the study will be CD107a expression by NK cells after stimulation during the chronic phase following SCI. Secondary endpoints will be TNF-alpha and IFN-gamma production

by the NK cells during the same time period.
The objective of the proposed longitudinal study is the analysis of the hypotheses that i) SCI impairs NK cell function throughout the post-acute and chronic phases after SCI and ii) the degree of impairment relates to lesion height and severity. A deeper understanding of the spinal cord injury-induced immune depression syndrome (SCI-IDS) is crucial to enabling strategies for prevention of infections which are associated with poor neurological outcome and elevated mortality.

Organizational Data

- DRKS-ID: **DRKS00009855**
- Date of Registration in DRKS: **2016/01/13**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EA1/001/09 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **G82 - Paraplegia and tetraplegia**

Interventions/Observational Groups

- Arm 1: **i) Traumatic spinal cord injury (AIS A-D): Th5 and above;**

  Each Patient will receive a blood withdrawal at day 5-7, 11-28 and at week 8-12 after the lesion. The NK cell function including cytotoxicity (CD107a Expression) and production of immunmodulatory cytokines (Interferon-Gamma and TNF-alpha) of patients and healthy controls was though PMA/ionomycin or K562 Stimulation Assays.
- Arm 2: **ii) Traumatic spinal cord injury (AIS A-D): Th6 and below;**
- Arm 3: **iii) Spinal Fracture;**
- Arm 4: **iv) Healthy controls**

Characteristics

- Study Type: **Non-interventional**

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- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor**
- Control: **Other**
- Purpose: **Prognosis**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

NK cell cytotoxicity (CD107a Expression) nach PMA/ionomycin through Flow Cytometry (FACS) 10 weeks after SCI

Secondary Outcome

NK cell cytokine (IFN-gamma and TNF-alpha) production after PMA/ionomycin Stimulation through flow cytometry (FACS) 10 weeks after SCI

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **SCI Units, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/10/17**
- Target Sample Size: **36**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Patients with acute isolated spinal cord injury (AIS A-D) planned for surgical stabilization and decompression, lesion may include more than 1 segment
- Patients with acute isolated spinal fracture planned for surgical stabilization, lesion may include more than 1 segment
- ≥ 2 spinal cord or vertebral lesions definable one from another
- Documented informed consent of the patient

Exclusion criteria

- Non-traumatic spinal cord injury
- 2 or more spinal cord or vertebral lesions definable one from another
- Severe polytrauma (definition: patients with severe injuries of life-sustaining organ systems, which per se and in the acute phase are life-threatening (e.g., severe pelvic trauma, severe body cavity injuries)
- Concomitant traumatic brain injury (TBI) (definition: i) Patients with persisting neurological deficit in consequence of the TBI, ii) patient with severe TBI (Glasgow Coma Scale ≤ 8), and iii) patients with intracranial pressure monitoring sensors.)
- Neoplasia and/or antineoplastic therapy
- Rheumatic disease, collagenosis, vasculitis or other autoimmune disease
- Preexisting chronic infectious disease (before the injury)
- Preexisting systemic steroid treatment
- Severe alcohol or drug addiction
- Pregnancy, lactation

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Private sponsorship (foundations, study societies, etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/12/18**

Trial Publications, Results and other documents

■ Paper **[---]***

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*