Title of protocol: The Effect of Preventive Drug Therapy on Central Pain in Patients with Spinal Cord Lesions
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Objectives:

To examine whether preventative pregabalin treatment prevents the development of neuropathic pain following spinal cord lesions (SCL).

Setting:

The Spinal Rehabilitation Department, Loewenstein Rehabilitation Medical Center, Raanana, Israel.

Study design:

Non-randomized, interventional study.

Methods:

Participants: 50 SCL patients. Inclusion criteria: age 18 and above; up to 3 months following traumatic or non-traumatic SCL; ability to give informed consent and cooperate. Exclusion criteria: pregnancy; neurological or other medical conditions that may interfere with sensation; neuropathic-like pain before recruitment (described as painful sensation of electric current, burning, numbness, tingling, pricking, or squeezing); being treated with pregabalin; blood creatinine levels >1.2; creatinine clearance <60; sensitivity to lactose. Informed consents will be obtained from the patients who conformed with the inclusion/exclusion criteria. Participants who do not cooperate, wish to withdraw, develop pregabalin side effects, or are transferred to another hospital, where treatment of the pain is changed, will be removed from the study.

Treatment: Participants will be sequentially allocated to 2 groups. One group will include 2/3 of the patients and will receive preventive pregabalin for 12 weeks; the second (control) group will include the other 1/3 of the patients and will not receive preventative analgesics. The dose of the preventive pregabalin will be 75mg×1 (once daily) for the first 3 days, and 75mg×2, for the rest of the treatment period, followed by a week of gradual dosage decrease until the preventive treatment stops.

In case of pain without neuropathic characteristics, treatment will be with paracetamol or NSAIDs, according to the decision of the attending physician in the Spinal Rehabilitation Department. If neuropathic pain, as described above, is diagnosed, the pregabalin dose may be increased up 600 mg/day in total. If the pain persists, the drug therapy may change according to the policy of the department.

Follow-up: Demographic and clinical data will be collected from the patients' medical records.

Before starting the preventive treatment, and at 6 and 12 weeks from start (and at the respective periods for the control group), patients will complete the following questionnaires: background data (only before start), 0-10 visual analogue scale for pain (VAS), the Pain Catastrophizing Scale, the Depression Anxiety and Stress Scale (DASS), the Body Vigilance Scale (BVS), and the DSM-V for post-traumatic stress disorder. At those times and at 3 and 9 weeks from start, patients will be interviewed about the development of pain. If pain is reported at the interviews or between them, patients will be asked to complete the McGill Pain Questionnaire to help characterize it.

A physician in the Spinal Rehabilitation Department will interview patients in the pregabalin group about one month after the start of treatment to identify suicidal thoughts, which are possible side effect.

At 6 and 12 months after being included in the study, participants will be interviewed about the development of pain to investigate the long-term effect of the treatment; if needed, they will complete the McGill Pain Questionnaire.

In case of discharge from the Spinal Rehabilitation Department before 12 weeks from inclusion in the study, treatment and follow-up will continue. Adverse events will be reported according to the Israeli Ministry of Health regulations.